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(2022) 11 DEL CK 0122

In the Delhi High Court

Case No : Civil Writ Petition No. 2554 Of 2012

Rajesh Chaudhary — APPELLANT

Vs

Govt. Sarvodaya Bal Vidyalaya & Ors — RESPONDENT

Date of Decision : 15-11-2022

Acts Referred:
Constitution Of India, 1950 — Article 226
Drugs And Cosmetics Act, 1940 — Section 22

Citation : (2022) 11 DEL CK 0122

Hon'ble Judges : C.Hari Shankar, J

Bench : Single Bench

Advocate : Jai Bansal, Abhishek Verma, Anuj Aggarwal, Ayushi Bansal, Arshya Singh, Sanyam Suri, Sanjeev Uniyal, Dhawal Uniyal

Final Decision : Dismissed

Judgement

C.Hari Shankar, J

1. Ubi jus, ibi remedium. A remedy can only follow a right. This is cardinal to the administration of justice, and no court, guided by the rule of law, can jettison the principle on sympathetic considerations.

Facts

2. Prashant, the son of the petitioner Rajesh Chaudhary was, at the time of occurrence of the unfortunate incident from which these proceedings emanate, in the VIIth standard in the Government Sarvodaya Bal Vidyalaya (hereinafter "the school").

3. A month prior thereto, the Directorate of Education (the DOE) had issued a circular dated 9th January 2012 for implementation of the mass deworming programme in government/government aided schools under its aegis. It was noted, in the said circular, that several children were found to be suffering from chronic intestinal worms, which caused listlessness, diarrhoea, abdominal pain, anaemia, etc.

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4. School based deworming was found to be a safe and simple solution. As such, the Directorate of Health Services (DHS), Govt. of National Capital Territory of Delhi (GNCTD) planned to implement a Mass Deworming Programme in all government/government aided schools under the DOE, with deworming scheduled to be carried out on 21st February 2012. On the said day, the children were to be administered chewable Mebendazole tablets after their mid-day meals. A pre-programme training schedule, for training one principal and one nodal teacher from each school, Education Officers and District Deputy Directors of Education (DDEs) was also envisaged.

5. The aforesaid circular dated 9th January 2012 was followed up by circulars dated 13th January 2012 and 13th February 2012.

6. The circular dated 13th January 2012 stipulated that the drugs to be administered to the students would be delivered to the schools by the CNSY (Chacha Nehru Sehat Yojna) team and that the chewable tablets would be administered to the children by the teachers. The circular also provided that, in the event of any post-administration problems, the CNSY team would be available to attend to them.

7. The circular dated 13th February 2012, which was issued in continuation of the circular dated 13th January 2012, stated that the medicines to be administered were being supplied by the Health Department of the GNCTD, who had already been requested to ensure that the medicines were of optimum quality vide letter dated 10th February 2012. The contact numbers of officers to be contacted in the event of emergency were also provided in the circular.

8. Instructions were also communicated to teachers of various schools regarding the protocol to be followed in administering the medicines. Among other things, the instructions required the teachers to administer the medicines after mid-day meals and to further ensure that the medicine was not administered on an empty stomach.

9. Prashant, as the monitor of his class (VII-B) was entrusted with the task of overseeing administration of the medicines to children in his class. According to the counter affidavit filed by the school in the present case, Prashant informed the teacher that 11 students in his class were on empty stomach. They were, therefore, given their mid-day meals and were administered the Mebendazole tablets after recess. The counter affidavit of the school also avers that Prashant had been having a headache for the past two days and had also taken two pain killer tablets that morning, which he did not disclose to the teachers.

10. The Petitioner has contended – and the school has denied – that, of 2,506 students in the school who were administered the Mebendazole tablet, 11 suffered symptoms of vomiting and gastric disturbance. 20 to 30 minutes after he consumed the tablet, Prashant felt dizzy and vomited. On being informed, the doctor in the coordination team advised that Prashant be given Oral Re-hydration Solution (ORS) which was, accordingly, administered to him. He, thereafter,

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vomited once again. It was at this point that, according to the counter affidavit filed by the school, Prashant informed the teachers that he had had two pain killer tablets that morning and had been having a headache for two days.

11. A short while later, a senior doctor reached the school. Prashant's parents, i.e. the petitioner and his wife, were also called. The petitioner admitted that he had given one pain killer tablet to Prashant that morning. Prashant admitted to having had a second tablet as he was not experiencing any relief with one tablet. The senior doctor referred Prashant to the Sanjay Gandhi Hospital, where he was admitted.

12. The Sanjay Gandhi Hospital, that very day, referred Prashant for Non-Contrast CT (NCCT) scan of the head. The scan was conducted at the Ganesh Diagnostic and Imaging Center.

13. The report of the NCCT scan reads thus:

"The study shows subtle hypodense area involving right frontotemporal lobe and part of right basal ganglia region suggestive of ? non specific ischemic changes.

Rest of the brain parenchyma appears normal.

No evidence of bleed is seen.

The ventricular system & basal cisterns are normal.

No midline shift is seen."

(Emphasis contained in the original report)

14. In view of the NCCT scan report, Prashant was referred to the G.B. Pant Hospital, where he was admitted the next day i.e. on 22nd February 2012.

15. As Prashant was exhibiting neurological symptoms, he was admitted to the neurology department in the G.B. Pant Hospital, from where he was discharged on 5th March 2012 after treatment. It was seen that Prashant had suffered a stroke. The exact clinical condition of Prashant, and his treatment protocol during his stay in the G.B. Pant Hospital stands concisely captured in the following communication dated 6th June 2012, from the acting Head of the Department of Neurology to the CMO in-charge of the medical record department in G.B. Pant Hospital:

"Dated: 06/06/2012

To

Dr. N.R Laskar

CMO I/C

Medical Record Department

G.B. Pant Hospital, New Delhi

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Subject: Regarding details of patient with reference to your letter no. - U.O. No. - 50(62)

MRD/GBPH/NHRC/2012

Sir,

As per your request details of patient name Prashant is enclosed for necessary action in this regard.

Prashant, 14 year male resident of H.No-691, Saini Mohalla, Nangloi, Delhi, was brought in acute stroke unit at G.B. Pant Hospital on 22-02-2012 at 4.15pm (Emergency number 1500/12) from Sanjay Gandhi Memorial Hospital, Mangolpuri, Delhi, Intensive care unit with history of acute onset lett sided hemiparesis on the same day. As stated by father he was given" de-worming agent in the school on that day. On examination patient was conscious and following commands but he had swallowing difficulty for which he was already on Ryle' s tube from the referring hospital. On examination his pulse rate was 88/ minute, regular, with all peripheral pulses well felt. Blood pressure in right arm was 110/70 mm Hg. There was left sided upper motor neuron type facial paralysis and hemiplegia on left side of body with motor power on left side of limbs being MRC grade 0/5. Immediate CT scan of head was performed which revealed hypodensity in right parietal and temporal areas. His routine investigation including hemogram, kidney function test, electrolytes. ECG and X-ray chest were normal. Liver function test revealed slight elevation in serum bilirubin. Two-D echocardiograpy was normal. Patient was admitted in general ICU/ward nine (CR No.-218276). Patient was treated with antiplatelet, lipid lowering agent and antibiotics. Physiotherapy was started by physiotherapist. Gastroenterology consultation was taken and his hepatic viral markers were negative. USG abdomen revealed normal study. Liver function test also turned to normal in few days. MRI brain was performed which showed wedge shaped peripheral based T1 hypo intense and T2 & FLAIR hyper intense lesion showing restriction on DWI involving right temporo-parieto-occipital grey white mater, right lentiform and caudate nucleus. Also a similar lesion was noted in right occipital region suggestive of right middle cerebral artery (MCA) territory infarct. CT angiogram was performed which showed right MCA occlusion, immediately after its origin. Color Doppler of bilateral carotid vessels was normal. Patient was discharged on 05-03-2012 with a diagnosis of young stroke with right middle cerebral artery (MCA) occlusion. At the time of discharge, he was conscious, oriented and accepting orally well, with motor power in left sided limbs were grade 0/5. Patient was advised to come for follow up in stroke clinic at G.B. Pant Hospital on Tuesday afternoon 2.00 PM after 15 days, but till date he has not turned up for the same.

Thanking you

Yours faithfully,

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(Dr. Vinod Puri)

Director Prof. & Acting Head"

(Italics and underscoring supplied)

16. That hypodensity of cerebral white matter is indicative of a stroke is also borne out by the following abstract of an article from the PubMed.gov website of the National Library of Medicine, which is widely regarded as one of the most authentic sources for diagnostic and medical information worldwide:

"Hypodensity of the cerebral white matter in patients with transient ischemic attack or minor stroke: influence on the rate of subsequent stroke. Dutch TIA Trial Study Group

J C van Swieten 1, L J Kappelle, A Algra, J C van Latum, P J Koudstaal, J van Gijn

* PMID: 1510358

* DOI: 10.1002/ana.410320209

Abstract

In a prospective study of 3,017 patients with transient ischemic attack or minor ischemic stroke from the Dutch Transient Ischemic Attack Trial, the presence or absence of diffuse hypodensity of the white matter on a baseline computed tomography (CT) scan of the brain was related to the occurrence of subsequent stroke. On entry, 337 patients were judged to have diffuse hypodensity of the white matter on CT; they were older (71.4 +/- 7.4 years versus 64.4 +/- 9.9 years), more often had hypertension (50% versus 41%), and more often had lacunar infarcts on CT scan (40% versus 26%) than did patients with normal white matter. Strokes, fatal or nonfatal, occurred in 51 (15%) of the patients with diffuse hypodensity of the cerebral white matter, compared to 217 (8%) in the group with normal white matter (crude hazard ratio, 2.0; 95% confidence interval, 1.4-2.7). After adjustment for age and other relevant entry variables, the hazard ratio was 1.6 (95% confidence interval, 1.2-2.2). In patients younger than 70 years the crude hazard ratio was 2.7 (95% confidence interval, 1.7-4.2). The distribution between the main subtypes of stroke was similar for patients with and those without diffuse hypodensity of the cerebral white matter: Intracerebral hemorrhage occurred in 6 and 9%, cortical infarction in 47 and 45%, and lacunar infarction in 34 and 29%, respectively. We conclude that hypodensity of the cerebral white matter in patients with transient ischemic attack or minor stroke is associated with an extra risk of future stroke, from large as well as from small vessels, and particularly in patients under 70 years old; this increase of risk is independent of other risk factors for stroke."

(Emphasis supplied)

17. For the purpose of the present petition, it is not necessary to delve any deeper into the medical treatment administered to Prashant. There is no dispute

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about the fact that he had, in fact, suffered a serious stroke on 21st February 2012 and that, as a result of the stroke, he suffered paralysis of the left side of his body which affliction, apparently, continues till date.

18. Alleging that the Prashant's medical condition was solely attributable to negligence on the part of school authorities and the doctors who attended to him at that time, and also that the stroke which Prashant sustained was the effect of the Mebendazole tablet administered to him, the petition seeks issuance of a writ of Mandamus to the respondents to pay compensation, to the petitioner, of Rs. 50,00,000/- and to reimburse the bills relating to the medical treatment of Prashant.

Respondents' stands

19. Counter affidavits, in response to the writ petition, have been filed by Respondents 1 (the School), 2 (DOE), 5 (Ministry of Health & Family Welfare) and 7 (Directorate of Health Services, Department of Health and Family Welfare, GNCTD).

Respondents 1 and 2

20. Respondents 1 and 2, in their counter affidavit, seek to submit that, prior to being administered the Mebendazole, the children had been cautioned not to take the medicine if they had taken any other medicine that day and not to have the medicine on an empty stomach. The children were also advised to drink extra water if they felt dizzy or nauseous. Despite this, Prashant, it is sought to be pointed out, never informed the teachers of the headache from which he had been suffering since the past two days or of the two pain killer tablets that he had consumed that morning, before being administered Mebendazole.

21. The counter affidavit asserts that no child, apart from Prashant, reported dizziness, vomiting or any other side effect after administration of Mebendazole. As against this, the petition alleges that 11 students, who had been administered Mebendazole along with Prashant, suffered gastric issues and vomiting and had to be hospitalised. In exercise of its jurisdiction under Article 226 of the Constitution of India, it is not possible for this Court to ascertain the correct position in that regard. Suffice it, however, to note that, even as per the petitioner, only 11 students in the school, apart from Prashant, suffered side effects consequent on administration of Mebendazole on 21st February 2012, and that they were discharged after basic medical treatment.

22. The counter affidavit of Respondent 1 emphasises the fact that, out of 2,506 students who had been administered Mebendazole in the school on 21st February 2012, it was Prashant alone who suffered neurological symptoms. The counter affidavit asserts that no negligence or dereliction of public duty could, in the circumstances, be alleged against Respondent 1.

Respondent 5 (MOHFW)

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23. Respondent 5 (the MOHFW), in its counter affidavit, submits that, consequent to directions issued by this Court on 30th April 2012 to the respondents to produce test reports in respect of the sample/batch of Mebendazole tablets from which tablets had been administered to children in the school, the matter was jointly investigated by the MOHFW and the State Drug Control Authority, Delhi Administration on 16th August 2012. Samples of Mebendazole were drawn under Section 22 of the Drugs and Cosmetics Act, 1940 and got tested by the Government Analyst, Central Drugs Laboratories (CDL), Kolkata. Additionally, the matter was also investigated by the Deen Dayal Upadhyaya (DDU) Hospital, which submitted the following report dated 10th July 2012:

"To

The Deputy Secretary

Health & Family Welfare Department,

Govt. Of NCT Delhi

9th Level, A-Wing, Delhi Sectt,

IP Estate, New Delhi

Sub: Complaint dated 27/02/2012 received from R.H. Bansal regarding "Drug having a sick child a serious condition."

Ref: NHRC Case No. 1845/30/0/2012/OC

Sir,

Please refer to your letter dated 21.06.2012 vide which a report on the above said NHRC matter has been sought.

In this regard it is to inform you that as per available records, 10 children aged 11-12 yrs reported to pediatric emergency on 21.02.2012 between 1 p.m. – 2.15 p.m. from Adarsh School, Vikas Puri, with history of taking medicine for worms. All the children had complaints with symptoms of Gastritis and Headache. All the children were vitally stable and were kept under observation paediatric ward and treated for Gastritis. They were later discharged by evening with directions for review in OPD-SOS-in emergency. None of the child was in serious condition.

Kindly acknowledge receipt.

Yours sincerely

(Dr. S.P. Barua

Additional Medical Superintendent (H.Q.)"

24. As against this, an investigation report, dated 16th August 2012, by the Drugs Inspector, CDSCO (Central Drugs Standard Control Organisation), by way

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of compliance with the directions for investigation issued by this Court in these proceedings, has also been placed on record by Respondent 5 with its counter affidavit, which acknowledges that no residual stock of Mebendazole was found in the school and that the tablets which were sent for testing were from a stock found in the store of the Additional Director, School Health Scheme. Mr. Bansal, learned counsel for the petitioner contends, therefore, that there was no meaningful compliance with the direction passed by this Court, to have the batch of Mebendazole tablets, from which tablets were administered to the students in the school, tested, and he appears to be correct.

25. In that view of the matter, reference to the report of the CDL, Kolkata, which has also been filed by Respondent 5, would not serve any useful purpose. Suffice it to state that Respondent 5 too, asserts that, as no serious side effects visited any of the students in the school, except Prashant, no allegation of negligence or want of care could be attributed to the respondents.

Respondent 7 (DHS)

26. Respondent 7, the DHS, has also filed a counter affidavit, in which attention has been invited to a report submitted by the World Health Organisation (WHO) to the United States Congress, which advocated administration of deworming treatment to school children and particularly advocated use of Mebendazole. It was also submitted that the stock of Mebendazole administered to school children had been donated by Deworm The World which was an international global initiative and was, prior to administration, tested by the Standard Analytical Laboratory (ND) Pvt. Ltd. which certified the drug to be of standard quality eligible for administration. The counter-affidavit of Respondent 7 also points out that similar Mebendazole treatment, for deworming, had been administered to school children across the country, who had tolerated the treatment without any serious adverse side effects.

27. Thus, the respondents, in one voice, have disclaimed all responsibility for the stroke and other complications, ultimately resulting in paralysis, sustained by Prashant on 21st February 2012 and the days that followed.

28. During the course of the pendency of the present proceedings before this Court, suggestions were also mooted as to whether the Governmental Authorities could afford any ex gratia compensation to Prashant and his family and takes steps to rehabilitate him in society. I may note that Mr. Anuj Aggarwal, learned standing counsel for the official respondents agreed, very fairly, to consideration of the case of Prashant for grant of ex gratia compensation and also rehabilitation, subject to the request that the case be not treated as a precedent.

Rival Contentions

29. I have heard Mr. Jay Bansal, learned counsel for the petitioner and Mr. Anuj Aggarwal, learned standing counsel for GNCTD and its associate departments, at some length.

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30. Mr. Bansal pointed out that, despite the direction of this Court to have the samples of Mebendazole, from which tablets were administered to students in Prashant's School, tested, that could not take place as no residual samples were available in the school. He also alleges that the tablets were not administered in accordance with the guidelines issued by the Governmental Authorities to teachers, which required that the tablets be not administered on empty stomach and to be administered only after consumption of mid-day meals. He further attributed negligence to the teachers for not having verified, from Prashant, as to whether he had taken, that day, any other medicines. Had they done so, points out Mr. Bansal, the teachers would have learned that Prashant had, in fact, consumed two pain killers that morning.

31. Mr. Bansal has relied on literature available on the internet with respect to Mebendazole and its side effects, which read thus:

(i) From the website drugs.com:

"Mebendazole Side Effects

Not all side effects for mebendazole may be reported. You should always consult a doctor or healthcare professional for medical advice. Side effects can be reported to the FDA here.

For the Consumer

Applies to mebendazole : oral suspension, oral table chewable

In addition to its needed effects, some unwanted effects may be caused by mebendazole. In the event that any of these side effects do occur, they may require medical attention.

If any of the following side effects occur while taking mebendazole, check with your doctor or nurse as soon as possible.

Rare

* Fever

* Skin rashe or itching

* Sore throat and fever

* Unusual tiredness and weakness

*

Some of the side effects that can occur with mebendazole may not need medical attention. As your body adjusts to the medicine during treatment these side effects may go away. Your health care professional may also be able to tell your about ways to reduce or prevent some of these side effects. If any of the following side effects continue, are bothersome or if you have any questions about them, check with your health care professional:

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Less common

* Abdominal or stomach pain or upset

* Diarrhea

* Nausea or vomiting

*

Rare

* Dizziness

* Hair loss

* Headache

For Healthcare Professionals

Applies to mebendazole : compounding powder, oral table chewable.

General

Since mebendazole is not well absorbed, few systemic side effects are reported. Side effects may be more likely and more severe in patients with underlying liver disease.

Gastrointestinal

Gastrointestinal side effects have included nausea, vomiting, diarrhea, and abdominal pain, especially when the intestinal parasite burden is great.

Hepatic

Increased liver function tests have been associated with mebendazone in patients with hepatic hydatid cysts.

Hepatic side effects have included transient charges in liver function tests and granulomatous hepatitis. These side effects have been reported with mebendazole was taken or prolonged periods and at dosages substantially above those recommended.

Hematologic

Bone marrow biopsy results during mebendazole- associated leucopenia or pancytopenia have revealed hypocellularity. These effects reverse upon drug discontinuation.

Hematologic side effects are unusual and reversible, but may be severe. Profound leucopenia, often accompanied by anemia and thrombocytopenia, has been reported. Pancytopenia and neutropenia have also been reported.

Dermatologic

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Dermatologic side effects have included rare reports of alopecia and angioedema, Rash, pruritus, urticaria, and flushing have also been reported.

Other

No evidence of hypersensitivity (eosinophilla, rash leukocytosis) accompanied the rare reports of drug fever. The fever may have been idiosyncratic or evidence of a reaction to drug-induced tissue necrosis in hydatid cysts.

Other side effects have included chills and drug fever.

Nervous system

Nervous system side effects have been reported rarely. These have included weakness, drowsiness, and seizures."

(ii) From the website www.rxlist.com:

"Vermox Side Effects Centre

Vermox (mebendazole) is used to treat infections caused by worms such as whipworm, pinworm, roundworm, and hookworm. It is also used to treat infections caused by more than one of these worms at the same time. It is an "antihelmintic," or anti-worm, medication. The brand name Vermox is no longer available in the U.S. Generic versions may still be available. Common side effects include stomach/ abdominal pain, vomiting, diarrehea, headache, dizziness, or drowsiness.

The dose of mebendazole for children and adults to treat whipworm, roundworm, and hookworm is 1 tablet taken morning and evening for 3 consecutive days. The dose to treat pinworm is 1 tablet, taken just once. Mebendazole may interact with seizure medications. Tell your doctor all medications you use. During pregnancy, mebendazole should be used only when prescribed. It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding.

Our Vermox (mebendazole) Side Effects During Centre provides a comprehensive view of available drug information on the potential side effects when taking this medication.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Vermox in Detail – Patient Information: Side effect

Stop taking mebendazole and seek emergency medical attention if you experience an allergic reaction (swelling of your lips, or face, shortness of breath; closing of your throat; or hives).

Other, less serious side effects may be more likely to occur. Continue to take mebendazole and talk to your doctor if you experience abdominal pain, diarrhea,

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or a fever.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Vermox Overview-Patient Information: Side Effects

SIDE EFFECTS: Stomach/abdominal pain, vomiting, diarrhea, headache, dizziness, or drowsiness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptl.

Tell your doctor immediately if any of these rate but very rare serious side effects occur: severe abdominal pain, easy bleeding/bruising, signs of serious infection (e.g., fever, persistent sore throat), unusual/extreme tiredness, seizures, weakness, dark or pinkish urine, yellowing eyes/skin.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

Vermox FDA Prescribing Information: Side Effects

(Adverse Reactions)

SIDE EFFECTS

Transient symptoms of abdominal pain and diarrhea have occurred in cases of massive infection and expulsion of worms. Hypersensitivity reactions such as rash, urticaria and angioedema have been observed on rare occasions. Very rare cases of convulsions have been reported."

(iii) From the website https://www.webmd.com:

"Side effects

List mebendazole side effects by likelihood and severity.

The following side effects are associated with mebendazole

Common side effects of mebendazole

Infrequent side effects of mebendazole

Diarrhea Less severe

Feel like throwing up Less severe

Stomach cramps Less severe

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Throwing up Less severe

Rare side effects of mebendazole

Decreased Neutrophils a Type of White Blood Cell Severe

Deficiency of Granulocytes a Type ofWhite Blood Cell Severe

Inflammation of Skin caused by an Allergy Severe

Itching Severe

Rash Severe

Reaction due to an Allergy Severe

Dizzy Less severe

Hair loss Less severe

Head Pain Less severe"

(iv) From the website http://levertox.nih.gov:

"MEBENDAZOLE

Overview

Case Report

Product Information

Chemical Formula and Structure

Other Reference Links

Overview

Mebendazole

Introduction

Mebendazole is an antihelminthic agent used commonly for roundworm (pinworm and hookworm) infections, trichinosis, capillariasis and toxocariasis and other parasitic worm (infections. Mebendazole when given for prolonged periods in high doses has been associated with elevations in serum enzyme levels, and rare instances of acute, clinically apparent liver injury have been linked to its use.

Background

Mebendazole (me ben' da zole) is a benzimidazole anthelmintic similar in structure and mechanism of action to thiabendazole and albendazole. The benzimidazoles act by selective binding to beta-tubulin of parasitic worms, causing their immobilization and death. Mebendazole and albendazole share similar anthelmintic activity, mebendazole generally being preferred for treatment of pinworm and roundworm infections, and albendazole (because it is

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better absorbed) for systemic parasitic infections such as echinococcosis and cysticercosis. Mebendazole was approved for use in the United States in 1974 and is indicated for therapy of common parasitic worm infections. Mebendazole is available generically and under the brand names Emverm and Vermox in 100 mg and 500 mg chewable tablets. The usual dose is 100 or 500 mg once (pinworm) or varying doses for 3 days (whipworm, hookworm and roundworm infections), or varying doses for longer periods, depending upon the indication. Side effects with single dose regimens are uncommon, but can include gastrointestinal upset, fever, headache, nausea, vomiting and diarrhea. With more extended therapy, gastrointestinal symptoms are the most frequent side effects and rare but potentially severe adverse effects include neutropenia, hypersensitivity reactions, hepatitis, angioedema, Stevens Johnson syndrome and toxic epidermal necrolysis.

Hepatotoxicity

Mebendazole when given in typical doses has not been associated with serum enzyme elevations, although the duration of therapy is usually short and monitoring for enzyme elevations has rarely been reported. With high dose therapy (which is now rarely used with the availability of albendazole), elevations in serum aminotransferase levels (2 to 10 times normal) can occur, but are usually well tolerated. There have been rare reports of acute liver injury due to mebenazole, particularly when it is given repeatedly or in higher doses. The onset is usually with fever and malaise within days of starting or restarting therapy. The pattern of serum enzyme elevations is typically hepatocellular, and jaundice is uncommon. The abnormalities usually resolve rapidly with stopping therapy. Signs of hypersensitivity (rash, fever and eosinophilia) are typical and liver biopsy may show granulomas.

Mechanism of Injury

Mebendazole acts by binding tubulin in parasitic worms, which it does with greater avidity than the tubulin in mammalian cells, but some of the toxicity of the benzimidazoles may be related to this tubulin-binding activity. In most instances of clinically apparent liver injury, hypersensitivity appears to be the cause.

Outcome and Management

Mebendazole is usually well tolerated and the liver injury reported with its use has been mild and self-limited in course. Patients with hypersensitivity and acute liver injury attributed to mebendazole should avoid repeat exposure. It is unknown whether there is cross sensitivity with other benzimidazoles (such as albendazole), but there probably is and switching to another class of anthelmintic agents is appropriate if therapy is still needed."

(v) From the wikepedia page of Mebendazole:

"Adverse effects

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Mebendazole sometimes causes diarrhea, abdominal pain and elevated liver enzymes. In rare cases, it has been associated with a dangerously low white blood cell count, low platelet count, and hair loss, with a risk of agranulocytosis in rare cases.

Drug interactions

Carbamazepine and phenytoin lower serum levels of mebendazole. Cimetidine does not appreciably raise serum mebendazole (in contrast to the similar drug albendabole), consistent with its poor systemic absorption.

Stevens-Johnson syndrome and the more severe toxic epidermal necrolysis can occur when menbendazole is combined with high doses of metronidazole.

Mechanism

Mebendazole is thought to work by selectively inhibiting the synthesis of microtubules in parasitic worms, and by destroying extant cytoplasmic microtubes in their intestinal cells, thereby blocking the uptake of glucose and other nutrients, resulting in the gradual immobilization and eventual death of the helminths.

Discontinuation in Unites States

The last manufacturer of mebendazole in the United States, Teva Pharmaceuticals, announced on October 7, 2011, they have ceased manufacture of this product. As of December, 2011, it is no longer available from any manufacturer in the USA. No reason was given publicly for this discontinuation. Mebendazole formulations can be made by a compounding pharmacy at the request of a doctor. Mebendazole is still distributed in international markets by Johnson and Johnson and a number of generic manufacturers."

32. Consequent to directions issued by this Court in the present proceedings, the present case was also referred to a three member medical board of the G.B. Pant Hospital comprising of Dir. Prof. M.M Mehndiratta of the Department of Neurology, Dr. Dharmendra Gupta, CMO and Dr. Sunil M. Rahuja, in-charge nursing home G.B. Pant Hospital, who furnished the following report dated 3rd August 2012:

"Dated 03/08/2022

To,

The Medical Superintendent

GB Pant Hospital, Delhi

Subject: Regarding submissions of cause of illness of Mr. Prashant

Sir,

As per your request dated (31/7/12 on title) a medical board comprising of

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Director-Profesor MM Mehndiratta, Dr. SM Rahoja and Dr. Dharmendra Gupta met on 3rd August 2012 at 11.30 am in room no. 505 seminar room, department of Neurology, GB Pant Hospital Delhi. After reviewing relevant papers medical board has made following observations.

Prashant, 14 year male resident of H.No.-691, Saini Mohalla, Nangloi, Delhi, was brought in acute stroke unit at GB Pant Hospital on 22-09-012 at 4.15 pm (Emergency number 1500/12) from Sanjay Gandhi Memorial Hospital, Mangolpuri, Delhi, Intensive care unit with history of acute onset left sided hemiparesis for one day. As stated by father he was given de-worming agent in the school. On examination patient was conscious and following commands but he had swallowing difficulty for which he was already on Ryle's tube from the referring hospital. On examination his pulse rate was 88/minute regular with all peripheral pulses well felt Blood Pressure in right arm was 110/70 mm Hg. There was left sided upper motor neuron type facial paralysis and hemiplegia on left side of body with motor power on left side of limbs being MRC grade 0/5. Immediate CT scan of head was performed which showed wedge shaped peripheral based Tl hypointense and T2 and FLAIR hyper intense lesion showing restriction on DW1 involving right temporo-parieto-occipital grey while matter, right external capsule, right lentiform and caudate nucleus suggestive of right middle cerebral artery (MCA) territory infarct. CT angiogram was performed which showed right MCA occlusion immediately after its origin. Color Doppler of bilateral carotid vessels was norms. His routine investigations including hemogram, kidney function test, electrolytes, ECG and X-ray chest were normal. Two-D echocardiography was normal. USG abdomen revealed normal study. Patient was admitted in general ICU/ward nine. He was treated with antiplatelet, lipid lowering agent and antibiotics. Physiotherapy was started by physiotherapist. Patient was discharged on 05-03-2012 in stable condition. At the time of discharge he was conscious, oriented and accepting orally well with motor power in left sided limbs were grade 0/5. Patient was advised to come for follow up in stroke clinic at GB Pant Hospital on Tuesday afternoon 2.00 PM but he has not reported for the same.

As per Meyler's Side Effects of Drugs: The International Encyclopaedia of Adverse Drug Reactions and Interactions; stroke is not listed as side effect of Mebendazole (photocopy enclosed).

Final Diagnosis: Left sided hemi paresis with right sided middle cerebral artery (MCA) infarct due to right MCA occlusion."

(Italics and underscoring supplied)

Analysis

33. Having heard learned counsel for both sides and perused the material on record, this Court, while deeply empathising with Prashant and the unfortunate fate that befell him, sincerely regrets that, within the parameters of the law within which it is bound, and which alone it is empowered to administer, it is not

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possible to provide succour either to Prashant or to the petitioner, in the manner that the petition seeks.

34. The extensive reference, by Mr. Bansal, to literature available on the internet with respect to Mebendazole and its side effects is not strictly relevant, and cannot be of any serious assistance to this case; it does, however, indicate that neurological symptoms cannot be recorded as a known side effect of Mebendazole. While some of the literature does refer to convulsions and seizures as a rare occurrence in Mebendazole patients, a holistic reading of the literature indicates that Mebendazole is not known to cause neurological symptoms in a vast majority of cases. In fact, Mr. Bansal, I must note, was candid in this regard, as he acknowledged that Prashant's case was probably one of the rarest of rare cases in which serious neurological effects followed upon administration of Mebendazole treatment.

35. And that, I may note, is the second nail in the coffin of the case that Mr. Bansal seeks, so assiduously, to advocate. There is, unfortunately, precious little – indeed, nothing – on the record, on the basis of which it can be said that the stroke and consequent paralysis suffered by Prashant was attributable, in any way, to the administration of Mebendazole to him in school.

36. It is obvious that, in order to claim himself to be entitled to compensation, especially in proceedings under Article 226 of the Constitution of India, the petitioner would have to establish, cumulatively, that (i) there was want of requisite care and caution while administering Mebendazole to Prashant, and (ii) the stroke and paralysis that he suffered was attributable to the Mebendazole administered to him. To establish (i), the petitioner would have to show, at the very least, that neurological symptoms were a known side effect of Mebendazole administration.

37. The record, however, indicates otherwise. The report of the three member committee of G.B. Pant Hospital, the NCCT Scan report dated 21st February 2012 of the Ganesh Diagnostic and Imaging Centre and the fact that, for two days prior to 21st February 2012, Prashant had been continuously complaining of a headache, leads one to infer that Prashant suffered from a pre-existing cranial condition, with a prominent brain lesion, which, in all probability, exacerbated the situation. The expert opinions requisitioned in the case support the diagnosis that, even at the time of his admission in the hospital, he had a cerebral infarct as a result of MCA occlusion. Whether the strokes suffered by Prashant were the mere sequel to the two days' headache that he had been suffering without any meaningful treatment, or whether it was a reaction to the pain killer administered by him on the morning of 21st February 2012, or whether the Mebendazole tablet administered to him in school contributed to the condition, is anybody's guess. Based on the literature that Mr. Bansal has himself placed on record, which does not indicate paralysis to be, in any case, a known complication of Mebendazole administration, it would be extremely hazardous for any Court, trained in the law, to return a finding that the stroke and paralysis

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sustained by Prashant was in any manner attributable to the Mebendazole tablet administered to him in school.

38. Significantly, out of 2,506 students in the school, who had been administered Mebendazole, only 11 – even as per the writ petition – suffered any kind of reaction with none of the students suffering any serious adverse effects. It cannot, therefore, be reasonably said that the stroke and paralysis sustained by Prashant were attributable to the Mebendazole administered to him.

39. As such, the requisite causal connect between the administration of Mebendazole to Prashant and the stroke and paralysis which he suffered, the onus to establish which was on the petitioner, is completely lacking in the present case.

40. Assuming, arguendo, as Mr. Bansal sought to submit, that Prashant was an example of one of the rarest of rare cases in which serious neurological symptoms followed administration of Mebendazole, the Court could not, in that event, mulct the school authorities or the Governmental Authorities with any tortious liability. Administration of deworming treatment to school children has been advocated by no less an authority then the WHO as being safe.

41. Let alone teachers, even doctors, administering therapeutic treatment to patients, cannot be expected to keep in mind every one-off chance, howsoever rare, of adverse side effects visiting a patient, while administering treatment. The scalpel, as is often said, cannot be wielded with a shaking hand. It is nobody's case that neurological side effects, let alone stroke or paralysis, were known complications of Mebendazole administration. Even it were to be assumed that, in extremely rare cases, such side effects could occur, that cannot be a ground to fasten, on the school authorities or the Governmental Authorities, any liability for the stroke and paralysis suffered by Prashant.

42. The teachers, who were entrusted with the task of monitoring the administration of Mebendazole, were only required to ensure that the medicine was not administered on an empty stomach, and that the child had his mid-day meal prior to administration. There was no stipulated requirement for the teachers to keep a track on any medication that the children might have earlier had. Perhaps more importantly, the petitioner has not placed, on record, any material to indicate, that Mebendazole is contraindicated in person who have had pain killers, or that Mebendazole, when administered to a person who has pain killers, had any possibility of exacerbating neurological symptoms, much less stroke and paralysis.

43. The principle of strict liability – which is but an avatar of the res ipsa loquitur doctrine and owes its origin to the celebrated decision in Rylands v. Fletcher1 - has, therefore, no application in the facts of the present case. Strict, or no-fault, liability applies only where the act done is hazardous in character. Mebendazole has been certified by the WHO as a safe drug, suitable for administration to children in school as deworming therapy. The petitioner has not placed any

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material on record to indicate that Mebendazole is commonly known as a drug which can cause serious health complications in children when administered.

44. Jurisprudentially, a right in the petitioner has to be counterbalanced by a duty on the respondent, and its breach. None of the respondents can be said to have been remiss in the duties cast on them. No want of due care and caution can be attributed to any of the respondents. Thus, on application of the ubi jus ibi remedium principle, the claim of the petitioner, in the suit, cannot be traced to any right that vests in him. It has, therefore, to fail.

Conclusion

45. While therefore, this Court empathises with the situation in which Prashant and his father, i.e. the petitioner, found themselves, it is unable to come to their aid.

46. Having heard learned Counsel for both sides, this Court regrets that it is unable to grant the prayers in the writ petition, insofar as they claim monetary compensation from the respondents for the hemiparetic reactions which were displayed in the case of Prashant.

47. However, Mr. Anuj Aggarwal, learned Standing Counsel for the GNCTD has, with commendable fairness, stated that, given the condition of Prashant, the Government would be willing to examine whether an ex gratia payment could be made to him. He also submits that the Government would examine the possibility of rehabilitation of Prashant, but states that this should not be treated as a precedent for other cases.

48. In view of the aforesaid, while declining the reliefs sought in the petition, the GNCTD is directed to consider the possibility of rehabilitation of the petitioner's son and of granting him some ex gratia payment for the agonies that he has suffered. For the said purpose, the petitioner if he so chooses, is permitted to appear through a representative before the concerned officers in the GNCTD at a time which Mr. Anuj Aggarwal would, on instructions, communicate.

49. This Court is sanguine that the GNCTD would act with all fairness in the present matter. The authorities are, additionally, requested to take a decision as expeditiously as possible, as this petition itself has remained pending in this Court for 10 years.

50. Subject to the said caveat, the petition is dismissed, with no orders to costs.

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