Clinical trial results:
An Open-Label, Single-Dose Study to Assess the Safety of 500- mg Mebendazole Chewable Formulation in Children 2 to 10 Years of Age, Inclusive

Summary

EudraCT number	2015-001226-42
Trial protocol	Outside EU/EEA
Global end of trial date	12 March 2010

Results information

Result version number	v1
This version publication date	06 July 2016
First version publication date	05 August 2015

Trial information

Trial identification

Sponsor protocol code	MEBENDAZOLGAI3002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01173562
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Johnson & Johnson Pharmaceutical Research & Development
Sponsor organisation address	Turnhoutseweg 30, 2340 Beerse, Belgium,
Public contact	Clinical Registry Group-JB BV, Johnson & Johnson Pharmaceutical Research & Development, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group-JB BV, Johnson & Johnson Pharmaceutical Research & Development, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 March 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 March 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of a mebendazole 500-mg chewable tablet formulation in a pediatric population (children 2 to 10 years of age, inclusive).

Protection of trial subjects:

The safety assessments included Adverse events, vital sign measurements (axillary temperature, pulse, respiratory rate, and Blood Pressure [BP]) and Physical examinations (including height and body weight).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 February 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Tanzania, United Republic of: 396
Worldwide total number of subjects	396
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	396
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 396 participants were enrolled and treated with a Single dose of Mebendazole 500 mg.

Period 1

Period 1 title	Open Label (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Mebendazole 500 mg

Arm description:

Participants received a single dose of Mebendazole 500-mg chewable tablet on Day 1.

Arm type	Experimental
Investigational medicinal product name	MEBENDAZOLE
Investigational medicinal product code	SUB08660MIG
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

A single Dose of Mebendazole Chewable tablet 500 mg administered.

Number of subjects in period 1	Mebendazole 500 mg
Started	396
Completed	390
Not completed	6
Noncompliance with study drug	6

Baseline characteristics

Reporting groups	
Reporting group title	Mebendazole 500 mg
Reporting group description:	
Participants received a single dose of Mebendazole 500-mg chewable tablet on Day 1.	

Reporting group values	Mebendazole 500 mg	Total	
Number of subjects	396	396	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	396	396	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65 to 84 years	0	0	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	4.6		
standard deviation	± 1.94	-	
Title for Gender Units: subjects			
Female	190	190	
Male	206	206	

End points

End points reporting groups

Reporting group title	Mebendazole 500 mg

Reporting group description:

Participants received a single dose of Mebendazole 500-mg chewable tablet on Day 1.

Subject analysis set title	Safety Analysis Set (SAS)
Subject analysis set type	Safety analysis

Subject analysis set description:

Safety Analysis Set (SAS) includes Participants who received a single dose of mebendazole 500 mg and contributed any safety data after the start of study treatment.

Primary: Number of Participants With Adverse Events (AEs) or Serious Adverse Events (SAEs)

End point title	Number of Participants With Adverse Events (AEs) or Serious Adverse Events (SAEs)[1]

End point description:

An AE is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.

End point type	Primary

End point timeframe:

Up to 3 days after study drug administration

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistics was planned to be performed on this primary endpoint.

End point values	Mebendazole 500 mg			
Subject group type	Reporting group			
Number of subjects analysed	396[2]			
Units: participants				
number (not applicable)				
Adverse Events	44			
Serious AEs	0			

Notes:

[2] - SAS

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Vital Signs

End point title	Number of Participants with Abnormal Vital Signs

End point description:

Vital signs included assessment of axillary temperature, pulse, respiratory rate, and BP on Day 1 and Day 3

End point type	Secondary

End point timeframe:

Up to 3 Days after study drug administration

End point values	Mebendazole 500 mg			
Subject group type	Reporting group			
Number of subjects analysed	396[3]			
Units: participants				
number (not applicable)	289			

Notes:

[3] - SAS

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Physical Examinations at End-of-Study (EOS)

End point title	Number of Participants with Abnormal Physical Examinations at End-of-Study (EOS)

End point description:

Physical examination included evaluation of body organs (Skin, Eyes, Ears, Nose, Throat, Head, Neck, Thyroid, Heart, Lung, Chest (include Breasts), Abdomen, Genitalia, Anorectal, Lymph nodes, Musculoskeletal, Neurological, Other)

End point type	Secondary

End point timeframe:

Up to 3 Days after study drug administration

End point values	Mebendazole 500 mg			
Subject group type	Reporting group			
Number of subjects analysed	396[4]			
Units: participants				
number (not applicable)	47			

Notes:

[4] - SAS

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 3 days after study drug administration	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.1
Reporting groups	
Reporting group title	Mebendazole 500 mg
Reporting group description: Participants received a single dose of Mebendazole 500-mg chewable tablet on Day 1.	

Serious adverse events	Mebendazole 500 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 396 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Mebendazole 500 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 396 (11.11%)		
Investigations			
Respiratory Rate			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Cardiac Murmur			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Respiratory Rate Increased			
subjects affected / exposed	2 / 396 (0.51%)		
occurrences (all)	2		
Nervous system disorders			

Dizziness			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	8 / 396 (2.02%)		
occurrences (all)	8		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	11 / 396 (2.78%)		
occurrences (all)	11		
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Abdominal Pain			
subjects affected / exposed	2 / 396 (0.51%)		
occurrences (all)	2		
Aphthous Stomatitis			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	10 / 396 (2.53%)		
occurrences (all)	10		
Nausea			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Oral Pain			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Hepatobiliary disorders			
Jaundice			

subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	5 / 396 (1.26%)		
occurrences (all)	5		
Asthma			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Rhonchi			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Rash Papular			
subjects affected / exposed	3 / 396 (0.76%)		
occurrences (all)	3		
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 396 (0.51%)		
occurrences (all)	2		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		
Urinary Tract Infection			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 October 2009	The overall reason for the amendment was to change in the protocol title to accurately reflect that medbendazole 500 mg is a new formulation of an existing drug (VERMOX®), but not a new drug, Replacement of oral temperature with axillary temperature, to clarify regarding stool samples, to address IRB concern on adverse events, Removal of reference to blood plasma and urine samples.
21 January 2010	The overall reason for the amendment was to modify wording of exclusion criteria and removal of reference to mebendazole as VERMOX.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported