Clinical trial results:
Mode of action of Moviprep:impact on distribution of intestinal fluid and colonic microbiota

Summary

EudraCT number	2010-021879-85
Trial protocol	GB
Global end of trial date	17 April 2012

Results information

Result version number	v1 (current)
This version publication date	05 January 2019
First version publication date	05 January 2019

Trial information

Trial identification

Sponsor protocol code	10050

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Nottingham
Sponsor organisation address	Jubilee Campus Wollaton Road , Nottingham , United Kingdom, NG8 1BB
Public contact	Professor Robin Spiller Nottingham Digestive Diseases Biomedical Research Unit Nottingham Digestiv, Nottingham Digestive Diseases Biomedical Research Unit, 0115 8231032, robin.spiller@nottingham.ac.uk
Scientific contact	Professor Robin Spiller Nottingham Digestive Diseases Biomedical Research Unit Nottingham Digestiv, Nottingham Digestive Diseases Biomedical Research Unit, 0115 8231032, robin.spiller@nottingham.ac.uk
Sponsor organisation name	University of Nottingham
Sponsor organisation address	Jubilee Campus Wollaton Road , Nottingham , United Kingdom, NG8 1BB
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Scientific contact	Professor Robin Spiller, Nottingham Digestive Diseases Biomedical Research Unit, 0115 8231032, robin.spiller@nottingham.ac.uk

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	17 April 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 April 2012
Global end of trial reached?	Yes
Global end of trial date	17 April 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Patients often have to take osmotic laxatives to prepare the colon for colonoscopy or barium enema. We are interested in how these work and whether taking the dose all at once or in divided doses will affect the water distribution in the small bowel.

Protection of trial subjects:

The National Research Ethics Service (NREC) ethics approval (version 2.0 dated 20th August 2010), approval number 10/H0906/50, was obtained on 29th August 2010.

Background therapy:

none all healthy volunteers

Evidence for comparator:

Comparator was same preparation given in divided or single dose

Actual start date of recruitment	08 September 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	United Kingdom: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

by public advert

Pre-assignment

Screening details:

Bowel symptom questionnaire to exclude functional bowel disorders

Pre-assignment period milestones

Number of subjects started	24
Number of subjects completed	24

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Study compared 2l with 1l in divided doses given on two consecutive days

Arms

Are arms mutually exclusive?	Yes
Arm title	Group1

Arm description:

Consumed 1l litre moviprep at 1300h on day 1 and repeated on day 2

Arm type	Active comparator
Investigational medicinal product name	Moviprep
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

1litre made by adding sachet A and B together in 1 litre of tap water
Sachet A contains the following active substances:

Macrogol 3350

Sodium sulfate anhydrous

Sodium chloride

Potassium chloride

100 g

7.500 g

2.691 g

1.015 g

Sachet B contains the following active substances:

Ascorbic acid

Sodium ascorbate

4.700 g

5.900 g

The concentration of electrolyte ions when both sachets are made up to one litre of solution is as follows:

Sodium

Sulfate

Chloride

Potassium

Ascorbate

181.6 mmol/L (of which not more than 56.2 mmol is absorbable)

52.8 mmol/L

59.8 mmol/L

14.2 mmol/L

29.8 mmol/L

Arm title	group 2

Arm description:

2l moviprep

Arm type	Active comparator
Investigational medicinal product name	Moviprep
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2litre made by adding 2sachet A and 2B together in 2 litre of tap water
Sachet A contains the following active substances:

Macrogol 3350

Sodium sulfate anhydrous

Sodium chloride

Potassium chloride

100 g

7.500 g

2.691 g

1.015 g

Sachet B contains the following active substances:

Ascorbic acid

Sodium ascorbate

4.700 g

5.900 g

The concentration of electrolyte ions when both sachets are made up to one litre of solution is as follows:

Sodium

Sulfate

Chloride

Potassium

Ascorbate

181.6 mmol/L (of which not more than 56.2 mmol is absorbable)

52.8 mmol/L

59.8 mmol/L

14.2 mmol/L

29.8 mmol/L

Number of subjects in period 1	Group1	group 2
Started	12	12
Completed	11	12
Not completed	1	0
Consent withdrawn by subject	1	-

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group1
Reporting group description: Consumed 1l litre moviprep at 1300h on day 1 and repeated on day 2	
Reporting group title	group 2
Reporting group description: 2l moviprep	
Subject analysis set title	all
Subject analysis set type	Per protocol
Subject analysis set description: all completing study	

Primary: small bowel water content

End point title	small bowel water content
End point description: AUC o-4 hours after ingestion	
End point type	Primary
End point timeframe: 0-4hours after ingestion	

End point values	Group1	group 2	all	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	12[1]	12	23	
Units: AUC ml.min				
number (not applicable)	1925	1653	1789	

Notes:
[1] - i failed to complete study

Statistical analyses

Statistical analysis title	statistics
Statistical analysis description: ANOVA	
Comparison groups	Group1 v group 2
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	272

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	612
Variability estimate	Standard deviation
Dispersion value	170

Notes:

[2] - ANOVA for effect of time and treatment

Adverse events

Adverse events information	
Timeframe for reporting adverse events: study days	
Adverse event reporting additional description: mild abdominal discomfort after moviprep ingestion	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15

Reporting groups	
Reporting group title	group1
Reporting group description: -	
Reporting group title	group2
Reporting group description: -	

Serious adverse events	group1	group2	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	group1	group2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)	4 / 12 (33.33%)	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	3 / 12 (25.00%)	4 / 12 (33.33%)	
occurrences (all)	3	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported