



## 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
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##### 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
Public contact	Emma Bradley, Nottingham Digestive Diseases Biomedical Research Unit, 0115 823090, emma.bradley@nottingham.ac.uk
Scientific contact	Professor Robin Spiller, Nottingham Digestive Diseases Biomedical Research Unit, 0115 8231032, robin.spiller@nottingham.ac.uk

Notes:

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**Paediatric regulatory details**

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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:

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**Results analysis stage**

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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:

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**General information about the trial**

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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:

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**Population of trial subjects**

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**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:

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**Subjects enrolled per age group**

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In utero	0
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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
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Number of subjects completed	24
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### Period 1

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

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

### Arms

Are arms mutually exclusive?	Yes
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Arm title	Group1
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Arm description:

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

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

<b>Arm title</b>	group 2
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Arm description:

2l moviprep

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

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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

<b>Number of subjects in period 1</b>	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 0-4 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 <sup>[1]</sup>	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 <sup>[2]</sup>
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	272

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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: -

<b>Serious adverse events</b>	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 %

<b>Non-serious adverse events</b>	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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported