



Clinical trial results:

A Phase 4 randomised, double-blind, placebo controlled, crossover trial Nitrofurantoin Macrocrystals 100 mg twice daily for six weeks in the treatment of overactive bladder symptoms associated with a negative mid stream urine culture and pyuria in patients with and without Multiple Sclerosis.

Summary

EudraCT number	2009-017939-18
Trial protocol	GB
Global end of trial date	14 October 2014

Results information

Result version number	v1 (current)
This version publication date	13 October 2019
First version publication date	13 October 2019

Trial information

Trial identification

Sponsor protocol code	08/0316
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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 College London
Sponsor organisation address	Gower Street, London, United Kingdom,
Public contact	Joint Research Office, Gower Street, London , United Kingdom, WC1E 6BT, Joint Research Office, Gower Street, London , United Kingdom, WC1E 6BT, ctimps@ucl.ac.uk
Scientific contact	Joint Research Office, Gower Street, London , United Kingdom, WC1E 6BT, Joint Research Office, Gower Street, London , United Kingdom, WC1E 6BT, ctimps@ucl.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	14 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 October 2014
Global end of trial reached?	Yes
Global end of trial date	14 October 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to determine whether treatment with Nitrofurantoin improves average voided volume in MS and non-MS patients presenting with symptoms of overactive bladder and pyuria with a negative mid stream urine culture.

Protection of trial subjects:

No specific measures in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

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)	2
From 65 to 84 years	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

2 subjects were enrolled onto the study

Period 1

Period 1 title	Baseline and main trial period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Only 2 patients were enrolled. Estimated numbers in each treatment arm are provided based on randomisation scheme.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Test Drug
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Nitrofurantoin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

100 mg twice daily for six weeks

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

100 mg twice daily for six weeks

Number of subjects in period 1	Test Drug	Placebo
Started	1	1
Completed	1	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Test Drug
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Primary Endpoint

End point title	Primary Endpoint ^[1]
End point description:	
End point type	Primary
End point timeframe:	
Only 2 patients were enrolled in the trial. No data analysis was done. The trial ended early due to recruitment problems.	

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: Only 2 patients were enrolled in the trial. No data analysis was done. The trial ended early due to recruitment problems.

End point values	Test Drug	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[2]	0 ^[3]		
Units: 0				
number (not applicable)				

Notes:

[2] - Only 2 patients were enrolled in the trial. No data analysis was done. The trial ended early due to

[3] - Only 2 patients were enrolled in the trial. No data analysis was done. The trial ended early due to

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events were recorded at all study visits.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Study Drug
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Study Drug	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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: 0 %

Non-serious adverse events	Study Drug	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Only 2 patients were enrolled in the trial. No SAEs were reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 July 2011	Change in incl/excl. criteria, new SmPC, clarification on IMPD.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported