



## 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 |
|-----------------------|---------|

#### 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 |

|                   |   |
|-------------------|---|
| 85 years and over | 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       |
| <b>Arm title</b>             | Test Drug |

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

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

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

| <b>Number of subjects in period 1</b> | 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 <sup>[1]</sup> |
| 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 <sup>[2]</sup> | 0 <sup>[3]</sup> |  |  |
| 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<sup>[1]</sup>

Timeframe for reporting adverse events:

Adverse events were recorded at all study visits.

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | Study Drug |
|-----------------------|------------|

Reporting group description: -

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported