



## Clinical trial results: The effect of Pregabalin on Pain progressing in Painful Diabetic Neuropathy

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2006-005630-21 |
| Trial protocol           | GB             |
| Global end of trial date | 19 May 2014    |

### Results information

|                                   |  |
|-----------------------------------|--|
| Result version number             | v1 (current)   |
| This version publication date     | 28 August 2020   |
| First version publication date    | 28 August 2020   |
| Summary attachment (see zip file) | Summary 2006-005630-21 (EudraCT study letter 18.09.19.pdf) |

### Trial information

#### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | RG_06-180 |
|-----------------------|-----------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | University of Birmingham  |
| Sponsor organisation address | Edgbaston, Birmingham, United Kingdom, B15 2TT  |
| Public contact               | Research Governance Team, University of Birmingham,<br>researchgovernance@contacts.bham.ac.uk |
| Scientific contact           | Research Governance Team, University of Birmingham,<br>researchgovernance@contacts.bham.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                       | 19 May 2014 |
| Is this the analysis of the primary completion data? | No          |
| Global end of trial reached?                         | Yes         |
| Global end of trial date                             | 19 May 2014 |
| Was the trial ended prematurely?                     | Yes         |

Notes:

## General information about the trial

Main objective of the trial:

To determine the effect of pregabalin on cerebral pain processing and sensory perception thresholds in diabetic patients with Painful Diabetic Neuropathy.

Protection of trial subjects:

Inclusion criteria :1. Type 1/type 2 diabetes as defined by the WHO Classification.2. Duration of diabetes of at least 5 years. 3. HbA1c should be <9% with <1% fluctuation of HbA1c levels over the past 6 months.4. Age between 18 and 70 years.

5. Women of childbearing potential must be using an acceptable method of contraception to prevent pregnancy when they are enrolled in the study and must agree to continue to practice an acceptable method of contraception for the duration of their participation in the study.

6. Must meet the specified criteria for PDN (see below) and have no risk factors for other causes for neuropathy

7. Willingness to sign the Center for Research Ethics Committee (COREC) approved consent form

Exclusion criteria: 1. Nursing mothers, pregnant women (excluded by a negative pregnancy test). 2. History of drug or alcohol dependence in the last 5 years 3. Patients with severe systemic disease other than diabetes which has as a recognized complication neuropathy or severe chronic pain 4. Patients with symptoms of neuropathic pain in the upper limbs alone 5. Significant changes in skin conditions in the areas to be tested which could alter sensation. 6. Patients currently taking medications that could affect symptoms of painful DN except acetaminophen (up to 3g/d) or aspirin (up to 325 mg/d). 7. Patients experiencing an increase in pain after analgesic medication washout to levels which in the view of the PI would require prohibited analgesic therapy within a 6 wk period. 8. Patients whose creatinine clearance is less than 70 ml/min or have significant hepatic disease (AST, ALT,  $\gamma$ GT >2 times upper limit for normal). TSH outside normal limits 9. History of previous kidney, pancreas or cardiac transplantation. 10. Serious or unstable medical or psychological state that may interfere with study participation. 11. Taking other drugs, insulin within 3 months of starting study. 12. Hypersensitivity to pregabalin or other study medication.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 01 July 2009 |
| 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: 88888 |
| Worldwide total number of subjects   | 88888                 |
| EEA total number of subjects         | 88888                 |

Notes:

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**Subjects enrolled per age group**

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|   |       |
|---|-------|
| 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)                      | 0     |
| From 65 to 84 years                       | 0     |
| 85 years and over                         | 88888 |

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## Subject disposition

### Recruitment

Recruitment details:

After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues.

### Pre-assignment

Screening details:

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### Period 1

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

Blinding implementation details:

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### Arms

| Arm title | Overall |
|-----------|---------|
|-----------|---------|

Arm description:

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|  |            |
|--|------------|
| Arm type                               | n/a        |
| Investigational medicinal product name | Pregabalin |
| Investigational medicinal product code |            |
| Other name                             |            |
| Pharmaceutical forms                   | Tablet     |
| Routes of administration               | Oral use   |

Dosage and administration details:

After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues.

|  |          |
|--|----------|
| Investigational medicinal product name | Placebo  |
| Investigational medicinal product code |          |
| Other name                             |          |
| Pharmaceutical forms                   | Tablet   |
| Routes of administration               | Oral use |

Dosage and administration details:

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| <b>Number of subjects in period 1</b> | Overall |
|---------------------------------------|---------|
| Started                               | 88888   |
| Completed                             | 88888   |

## Baseline characteristics

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Overall |
|-----------------------|---------|

Reporting group description:

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| Reporting group values  | Overall | Total |  |
|---|---------|-------|--|
| Number of subjects  | 88888   | 88888 |  |
| Age categorical   |         |       |  |
| After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues. |         |       |  |
| Units: Subjects   |         |       |  |
| Not applicable  | 88888   | 88888 |  |
| Gender categorical  |         |       |  |
| After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues. |         |       |  |
| Units: Subjects   |         |       |  |
| Not applicable  | 88888   | 88888 |  |

## End points

### End points reporting groups

|   |         |
|---|---------|
| Reporting group title   | Overall |
| Reporting group description:<br>After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues. |         |

### Primary: Not applicable

|   |                               |
|---|-------------------------------|
| End point title   | Not applicable <sup>[1]</sup> |
| End point description:<br>After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues. |                               |
| End point type  | Primary                       |
| End point timeframe:<br>After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain.   |                               |

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: Justification - No statistical analyses have been specified as the trial was terminated early. After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues.

|                             |                      |  |  |  |
|-----------------------------|----------------------|--|--|--|
| <b>End point values</b>     | Overall              |  |  |  |
| Subject group type          | Reporting group      |  |  |  |
| Number of subjects analysed | 88888 <sup>[2]</sup> |  |  |  |
| Units: n/a                  | 88888                |  |  |  |

Notes:

[2] - 88888 is referring to not applicable due to the data integrity issues.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain.

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

### Dictionary used

|                    |     |
|--------------------|-----|
| Dictionary name    | n/a |
| Dictionary version | 0   |

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

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#### 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: No adverse events have been specified as the trial was terminated early. After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain. For the purposes of data entry 88888 is referring to not applicable due to the data integrity issues.

## 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

After a regulatory inspection the trial was closed as the inspection identified issues with data integrity. Our Clinical Trials Oversight Committee have made a decision that these results should not be in the public domain.

Notes: