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, researchgovernance@contacts.bham.ac.uk
Scientific contact	Research Governance Team, University of Birmingham, 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 between18 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 be 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, γGT >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:

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

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:

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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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Number of subjects in period 1	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			
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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:

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Primary: Not applicable

End point title	Not applicable[1]

End point description:

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End point type	Primary

End point timeframe:

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.

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	88888[2]			
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

Adverse events information[1]

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 %

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

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.

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Notes: