Clinical trial results:
Vildalgliptin and Glucose Variability in Type 2 Diabetes

Summary

EudraCT number	2011-006049-14
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 2011-006049-14 (EudraCT study letter 18.09.19.pdf)

Trial information

Trial identification

Sponsor protocol code	RG_11-165

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:

Patients will be given Vildagliptin 50mg daily and metformin or continue with their sulphonylurea and metformin algorithm to determine if Vildagliptin is effective in reducing cardiac risk profiles in South Asians. Patients diagnosed with Type II diabetes will be recruited into a 12-week, open labeled, randomized, case-controlled clinical study.

Protection of trial subjects:

Inclusion Criteria:

1. Type 2 diabetes of at least 6 months duration;
2. HbA1c should be 7-9%.
3. Established on metformin and sulphonylurea combination therapy for at least 3 months
4. Body mass index from 25 kg/m2 to 45 kg/m2
5. Stable body weight (<10% variation for the 3 months prior to screening
6. Age between 18 and 75 years:
7. Women of childbearing potential must be using contraception to prevent pregnancy
8. Sign the NHS REC approved consent form

Exclusion Criteria:

1. Nursing mothers, pregnant women (excluded by a negative pregnancy test).
2. Patients with a history of drug/alcohol abuse
3. Abnormal liver function tests
4. Severe chronic renal failure (GFR<50 ml/min) or diabetic nephropathy
5. Patients with a history of hypersensitivity to Vildagliptin or any other ingredients found in the study medication.
6. Failure to provide informed consent

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	20 December 2012
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	Not blinded

Arms

Arm title	Overall

Arm description:

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Arm type	n/a
Investigational medicinal product name	Vildagliptin
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	Metformin
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: 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: