# Clinical trial results:
# A randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of one dose of imeglimin versus placebo after 18 weeks of treatment in subjects with type 2 diabetes mellitus

## Summary

| | |
|---|---|
| EudraCT number | 2013-001539-35 |
| Trial protocol | HU LV |
| Global end of trial date | 23 October 2014 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 27 October 2021 |
| First version publication date | 27 October 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | PXL008-009 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | POXEL SA |
| Sponsor organisation address | 259/261 avenue Jean Jaurès, LYON, France, 69007 |
| Public contact | Pascale Fouqueray, POXEL S.A., +33 437372010, pascale.fouqueray@poxelpharma.com |
| Scientific contact | Pascale Fouqueray, POXEL S.A., +33 437372010, pascale.fouqueray@poxelpharma.com |

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 | 24 April 2015 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 23 October 2014 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To assess the effect of imeglimin versus placebo on glucose tolerance during a 3-hour Oral Glucose Tolerance Test (OGTT) after 18 weeks of treatment in type 2 diabetic subjects.

Protection of trial subjects:

Subjects provided their written consent to participate in the study after having been informed about the nature and purpose of the study, participation/termination conditions, and risks and benefits of treatment. The subject information sheet in the local language and prepared in accordance with the ICH GCP guidance was provided by the sponsor for the purpose of obtaining informed consent. The subject's written informed consent to participate in the study must have been given before any study-related activities were carried out. Whenever important new information became available that was relevant to the subject's consent, the written subject information sheet and any other written information provided to subjects were revised by the Sponsor and submitted again to the IEC/IRB for review and favourable opinion. The agreed, revised information was forwarded to each subject in the study. The Investigator explained the changes to the previous version and the subject was asked to sign the new version. Subjects were free to discontinue the study at any time without giving their reasons.
To overcome the risk to expose T2DM subjects to inappropriate glycaemic levels, some proactive measures were implemented. First, the upper level of HbA1c inclusion criteria at randomisation was limited to 9.5% to avoid highly uncontrolled subjects entering the study. Second, fasting plasma glucose [FPG] was closely monitored throughout the study by the subject (glucometer) and by the Investigator at each visit and whenever necessary. Thresholds were defined following the Food and Drug Administration (FDA) guidance to withdraw subjects whose glycaemic parameters continued to deteriorate during the study period so that rescue therapy could be initiated.

Background therapy:

No background therapy was allowed during the study.

Evidence for comparator:

This mechanistic study was designed to evaluate the efficacy of imeglimin on both fasting and postprandial glycaemic control compared to placebo after 18 weeks of treatment duration, and their respective participation in decreasing HbA1c.

| | |
|---|---|
| Actual start date of recruitment | 12 August 2013 |
| 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 | Hungary: 26 |
| Country: Number of subjects enrolled | Latvia: 19 |
| Country: Number of subjects enrolled | Romania: 14 |
| Worldwide total number of subjects | 59 |
| EEA total number of subjects | 59 |

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) | 50 |
| From 65 to 84 years | 9 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Among the 13 sites initiated, this study was conducted at 9 recruiting centres in 3 countries (4 centres in Hungary, 2 centres in Latvia, and 3 centres in Romania). Four sites were inactive (1 centre in Hungary and 3 in Romania).
First subject screened: 12Aug2013 - Last subject randomized: 11Jun2014

### Pre-assignment

Screening details:

Subjects were screened within 3 weeks, followed by a 4-week single blind placebo wash-out period.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Imeglimin 1500 mg twice daily |

Arm description: -

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Imeglimin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

3×500 mg tablet of imeglimin twice daily for 18 weeks

| | |
|---|---|
| **Arm title** | Placebo |

Arm description: -

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

Dosage and administration details:

3 tablets of placebo twice daily for 18 weeks

| **Number of subjects in period 1** | Imeglimin 1500 mg twice daily | Placebo |
|---|---|---|
| Started | 30 | 29 |
| Completed | 25 | 18 |
| Not completed | 5 | 11 |
| Consent withdrawn by subject | 4 | - |
| Adverse event, non-fatal | - | 1 |
| Lack of efficacy | 1 | 9 |
| Protocol deviation | - | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Imeglimin 1500 mg twice daily |
| Reporting group description: - | |
| Reporting group title | Placebo |
| Reporting group description: - | |

| Reporting group values | Imeglimin 1500 mg twice daily | Placebo | Total |
|---|---|---|---|
| Number of subjects | 30 | 29 | 59 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 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 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 58.4 | 54.3 | |
| standard deviation | ± 8.0 | ± 8.9 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 18 | 13 | 31 |
| Male | 12 | 16 | 28 |
| BMI | | | |
| Units: kg/m² | | | |
| arithmetic mean | 32.83 | 32.91 | |
| standard deviation | ± 4.95 | ± 4.26 | - |
| HbA1c | | | |
| Units: percent | | | |
| arithmetic mean | 8.12 | 8.14 | |
| standard deviation | ± 0.56 | ± 0.61 | - |
| Fasting Plasma Glucose | | | |
| Units: mmol/L | | | |
| arithmetic mean | 11.33 | 10.25 | |
| standard deviation | ± 2.53 | ± 1.92 | - |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Imeglimin 1500 mg twice daily |
| Reporting group description: - | |
| Reporting group title | Placebo |
| Reporting group description: - | |

### Primary: Change in glucose AUC during the 3-hour OGTT from baseline to Week 18 versus placebo

| | |
|---|---|
| End point title | Change in glucose AUC during the 3-hour OGTT from baseline to Week 18 versus placebo |
| End point description: | |

| | |
|---|---|
| End point type | Primary |
| End point timeframe: | |
| Baseline to Week 18 (End of Treatment) | |

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: mmol/L·min | | | | |
| arithmetic mean (standard deviation) | -800.1 (± 620.0) | -257.3 (± 586.2) | | |

### Statistical analyses

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Statistical analysis description: | |
| Change from baseline to Week 18 in glucose AUC during the OGTT was assessed with an analysis of covariance (ANCOVA) model, with country and treatment effect fitted as factors and baseline AUC glucose fitted as a covariate. This analysis was performed on the ITT population using LOCF. | |
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -429.6 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -678 |
| upper limit | 181.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 123.7 |

## Secondary: Change in HbA1c from baseline to Week 18 versus placebo

| | |
|---|---|
| End point title | Change in HbA1c from baseline to Week 18 versus placebo |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 18 (End of Treatment) | |

| **End point values** | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: percent | | | | |
| arithmetic mean (standard deviation) | -0.44 (± 0.76) | 0.16 (± 1.00) | | |

### Statistical analyses

| **Statistical analysis title** | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Statistical analysis description: | |
| Change from baseline to Week 18 was to be assessed with an ANCOVA model with country and treatment effect fitted as factors and baseline HbA1c fitted as a covariate. The analysis was performed on the ITT population using LOCF (when applicable). | |
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.62 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.11 |
| upper limit | -0.14 |

| | |
|---|---|
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.24 |

## Secondary: Change in Predose FPG from baseline to Week 18 versus placebo

| | |
|---|---|
| End point title | Change in Predose FPG from baseline to Week 18 versus placebo |

End point description:

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline to Week 18 (End of Treatment)

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | -1.77 (± 2.42) | -0.41 (± 1.91) | | |

### Statistical analyses

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|

Statistical analysis description:

Change from baseline to Week 18 was to be assessed with an ANCOVA model with country and treatment effect fitted as factors and baseline predose FPG as a covariate. The analysis was performed on the ITT population using LOCF (when applicable).

| | |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.092 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.97 |
| upper limit | 0.15 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.53 |

| Secondary: Change in Postdose FPG from baseline to Week 18 versus placebo | |
|---|---|
| End point title | Change in Postdose FPG from baseline to Week 18 versus placebo |

End point description:

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline to Week 18 (End of Treatment)

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | -2.26 (± 2.60) | -0.53 (± 1.71) | | |

## Statistical analyses

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|

Statistical analysis description:

Change from baseline to Week 18 was to be assessed with an ANCOVA model with country and treatment effect fitted as factors and baseline Postdose FPG fitted as a covariate. The analysis was performed on the ITT population using LOCF (when applicable).

| | |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.022 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -1.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.25 |
| upper limit | -0.18 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.52 |

| Secondary: Change in Rate sensitivity from baseline to Week 18 versus placebo | |
|---|---|
| End point title | Change in Rate sensitivity from baseline to Week 18 versus placebo |

End point description:

| | |
|---|---|
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 18 (End of Treatment) | |

| **End point values** | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: pmol.m^-2.mM^-1 | | | | |
| arithmetic mean (standard deviation) | 223.20 (± 385.75) | 39.20 (± 273.54) | | |

**Statistical analyses**

| **Statistical analysis title** | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.051 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 183.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.17 |
| upper limit | 367.67 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 91.86 |

**Secondary: Change in insulinogenic index from baseline to Week 18 versus placebo**

| End point title | Change in insulinogenic index from baseline to Week 18 versus placebo |
|---|---|
| End point description: | |

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| Baseline to Week 18 (End of Treatment) | |

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: not applicable | | | | |
| arithmetic mean (standard deviation) | 2.57 (± 2.40) | 0.69 (± 2.89) | | |

**Statistical analyses**

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.025 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.24 |
| upper limit | 3.34 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.77 |

**Secondary: Change in glucose sensitivity from baseline to Week 18 versus placebo**

| End point title | Change in glucose sensitivity from baseline to Week 18 versus placebo |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Week 18 (End of Treatment)

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: pmol.min^-1.m^-2.mM^-1 | | | | |
| arithmetic mean (standard deviation) | 14.98 (± 18.50) | 0.96 (± 13.22) | | |

**Statistical analyses**

| **Statistical analysis title** | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.004 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 12.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.2 |
| upper limit | 20.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 4.01 |

| **Secondary: Change in Stumvoll index from baseline to Week 18 versus placebo** | |
|---|---|
| End point title | Change in Stumvoll index from baseline to Week 18 versus placebo |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 18 (End of Treatment) | |

| **End point values** | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: No unit | | | | |
| arithmetic mean (standard deviation) | 0.0188 (± 0.0139) | 0.0056 (± 0.0150) | | |

**Statistical analyses**

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.0133 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.0058 |
| upper limit | 0.0208 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.0037 |

**Secondary: Change in incremental AUC 0-180 C-Peptide / incremental AUC 0-180 Glucose from baseline to Week 18 versus placebo**

| End point title | Change in incremental AUC 0-180 C-Peptide / incremental AUC 0-180 Glucose from baseline to Week 18 versus placebo |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Week 18

| End point values | Imeglimin 1500 mg twice daily | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 29 | 28 | | |
| Units: No unit | | | | |
| arithmetic mean (standard deviation) | 0.119 (± 0.132) | 0.028 (± 0.058) | | |

**Statistical analyses**

| Statistical analysis title | Imeglimin 1500 mg bid versus Placebo |
|---|---|
| Comparison groups | Imeglimin 1500 mg twice daily v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.091 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.033 |
| upper limit | 0.149 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.029 |

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: | |
| From Informed Consent Form signature up to to the end of the follow-up period | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.1 |

| Reporting groups | |
|---|---|
| Reporting group title | Imeglimin 1500 mg twice daily |
| Reporting group description: - | |
| Reporting group title | Placebo |
| Reporting group description: - | |

| Serious adverse events | Imeglimin 1500 mg twice daily | Placebo | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 29 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Meigs' syndrome | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 29 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 29 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 29 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| **Non-serious adverse events** | Imeglimin 1500 mg twice daily | Placebo | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 30 (20.00%) | 14 / 29 (48.28%) | |
| Cardiac disorders | | | |
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 29 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Nervous system disorders | | | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 3 / 29 (10.34%) | |
| occurrences (all) | 0 | 3 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 5 / 30 (16.67%) | 12 / 29 (41.38%) | |
| occurrences (all) | 7 | 13 | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 06 December 2013 | The purpose of this amendment was:<br>- To change 1 study procedure (OGTT at 6 weeks became optional).<br>- To change 1 inclusion criteria (broaden HbA1c eligible lower range, without affecting subject's safety and efficacy assessment).<br>- To clarify the CGM procedure.<br>- To correct inconsistencies in the protocol.<br>- To include administrative changes. |
| 29 April 2014 | The purpose of this amendment was:<br>- To include administrative change concerning the laboratory assigned for bioanalysis.<br>- To extend the study period due to recruitment being slower than expected.<br>- To update the title and contact details of the Sponsor's Medical Responsible Person. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported