Open Label Single Period Pilot Clinical Trial to Standardize Procedures for Evaluation of Glucose Dependent Insulin Secretion in Subjects with Type 2 Diabetes Mellitus

Published: 07-02-2011
Last updated: 27-04-2024

To standardize the procedures and analyses to support evaluation of glucose dependent insulin secretion in Type 2 Diabetes Mellitus in subjects with Type 2 Diabetes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON36208

Source
ToetsingOnline

Brief title
Pilot study glucose infusion in type II diabetes patients

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, insulin secretion

Research involving
Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Diabetic, Insulin Secretion

Outcome measures

Primary outcome

Standardizing the methodology

Pharmacodynamics

Pharmacokinetics

Safety

Secondary outcome

N/A

Study description

Background summary

In this study you will not participate in an investigation with a new compound, but you will participate in a pilot study in which the reactions of patients with Diabetes Mellitus Type 2 will be evaluated. In order to participate in this study, you are not allowed to take your own diabetic medication for a maximum of 1.5 days. In order to obtain a pre-defined blood sugar level, you will receive a temporary insulin infusion administered with a pump. In Part 1 you will also receive an infusion of glucose solution. During this study you will receive insulin. Insulin is an hormone produced by the human body naturally. Insulin is involved in the regulation of the metabolism of sugar and fat in the body. Insulin causes cells in the liver, muscle, and fat tissue to take up blood sugar (glucose) from the blood, storing it as a long-term energy depot in the liver and muscle. When the natural control of insulin production by the body fails, the complication diabetes mellitus will develop. The insulin

that will be administered temporarily, is used on a large scale and is internationally registered (NovoRapid) and approved.

Study objective

To standardize the procedures and analyses to support evaluation of glucose dependent insulin secretion in Type 2 Diabetes Mellitus in subjects with Type 2 Diabetes.

Study design

Design:
an open-label, single period pilot clinical study in a maximum of six type 2 diabetes mellitus patients to standardize procedures for evaluation of glucose dependent insulin; each subject will receive a continuous intravenous infusion of insulin for up to 12 hours starting on Day -1 of the study, followed by a 160-minute GGI procedure conducted on Day 1 of the study: glucose (20% glucose) will be administered as a stepwise, graded infusion of 2, 4, 6, and 10 mg/kg/min (down-regulated to 8 mg/kg/min at last step if applicable), each infusion step should be maintained over exactly 40 minutes, all subjects will undergo a 10 hour overnight fast before initiation of the GGI. Of these 6 subjects, 4 subjects may be selected randomly to participate in Part 2 of the study in which only the insulin infusion is given during the day.

Procedures and assessments
Screening and follow-up:
clinical laboratory, physical examination, weight, 12-lead ECG, vital signs (including oral temperature), urine drug screen; at eligibility screening: medical history, HbA1C, HBsAg, anti HCV, anti-HIV 1/2; weight and vital signs to be repeated upon admission. For Part 2, no screening visit or follow-up visit is necessary.

Observation period:
Part 1: one period in clinic from -24 h before start of the GGI up to completion of the weaning procedure in the afternoon of Day 1
Part 2: one period in clinic from -12 h before start of the insulin infusion up to completion of the insulin infusion the afternoon of Day 1

Blood sampling:
for glucose (Part 1 and Part 2): every 30 minutes during the insulin infusion.
for glucose (Part 1 only): 10 and 3 minutes before the start of the GGI, and 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 130, 140, 150 and 160 min after start of GGI
for C-peptide (Part 1 only): 10 and 3 minutes before the start of the GGI, and 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 130, 140, 150 and 160 min after start of GGI

for insulin (Part 1 only): 10 and 3 minutes before the start of the GGI, and 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 130, 140, 150 and 160 min after start of GGI
for GLP-1/glucagon and for archive(Part 1 only): 10 minutes before the start of the GGI and 40, 80, 120 and 160 min after start of GGI

Urine sampling:
for glucose (Part 1 only): interval from 15 min before start of GGI up to 160 min after start of GGI

Safety assessments:
adverse events: throughout the study; vital signs: 12 h and 60 min before GGI and prior to discharge; blood sample for glucometer (Part 1) and iSTAT/YSI (Part 2): every hour during insulin infusion; Only Part 2: 10 and 3 minutes before GGI and 40, 80, 120 and 160 min after start of GGI and 10 times during the weaning procedure

Insulin Infusion Procedures:
IV catheter placement: ~60 min before start of the insulin infusion ; insulin infusion: 11 * 1 h before GGI (only Part 1), blood glucose concentration should be kept around 5.6 mmol/L

GGI Procedure:
Part 1 only: infusion of glucose: 0 - 160 min on Day 1, glucose (20% glucose) will be administered as a stepwise, graded infusion of 2, 4, 6, and 10 mg/kg/min (down-regulated to 8 mg/kg/min at last step if applicable), each infusion step should be maintained over exactly 40 minutes

Bionalysis:
analysis of glucose samples using a clinical chemistry method by PRA
analysis of C-peptide samples using a clinical chemistry method by PRA
analysis of insulin samples using a clinical chemistry method by PRA
analysis of GLP-1/glucagon samples using a validated method by PRA

Intervention

Insulin infusion

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

Public
PRA International EDS

Stationsweg 163
9471 GP Zuidlaren
NL
Scientific
PRA International EDS

Stationsweg 163
9471 GP Zuidlaren
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male, 18-55 years, inclusive
BMI is less than or equal to 38.0 kg/m2
Type 2 Diabetes Mellitus Patient

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study or in case of donating more than 1.5 liter of blood in the 10 months prior the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2011
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NovoRapid
Generic name:	Insulin Aspart
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-02-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-02-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-03-2011

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-03-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-05-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-05-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-000449-19-NL
CCMO	NL35645.056.11