Evaluation of Continuous Glucose Monitoring as a Tool to Measure Glucoregulatory Effects of a Twice Daily Oral Insulin Secretagogue

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Primary:To estimate the treatment effects of vildagliptin 50 mg PO BID on 24h weighted-mean glucose (WMG), using CGM and plasma glucose, collected at the end of a two-week treatment period.Secondary:1) To estimate the treatment effects of...

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

Summary

ID

NL-OMON37821

Source
ToetsingOnline

Brief title
CGM main Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 2 Diabetes Mellitus: bloodglucose

Research involving
Human

Sponsors and support

Primary sponsor: PRA International EDS

Source(s) of monetary or material Support: Pharmaceutische Industrie

Intervention

Keyword: Blood glucose, Type 2 diabetes mellitus, Vildagliptin

Outcome measures

Primary outcome

The primary endpoints for analysis include: weighted mean glucose and HbA1c.

Other endpoints for analysis include circulating GLP-1, glucagon and other analytes and CGM measurements. Blood will be collected for archived samples that may be analyzed for other study specific biomarkers.

Safety and tolerability will be monitored throughout the study by clinical assessment of adverse experiences and by vital sign measurements, physical examinations, 12-lead ECGs, standard laboratory safety tests (hematology, chemistry, and urinalysis). These procedures may also be performed at various unscheduled time points, if deemed clinically necessary, by the Investigator.

Secondary outcome

N/A

Study description

Background summary

In this study the volunteers will participate in an investigation with a medicine used to treat Type 2 Diabetes Mellitus with the purpose to evaluate a new method to measure blood glucose (blood sugar) profiles in Type 2 Diabetes Mellitus patients.
Type 2 diabetes mellitus is a major and still increasing health problem. There is still a continued unmet need for medications that can lower blood glucose

levels significantly.
In the present clinical practice, fasting blood glucose levels are typically used to measure blood glucose levels in diabetic patients, sometimes with the additional determination of several (generally 2 to 4) blood glucose concentrations over the day.
The above-mentioned measurements are however not capable of capturing the rapid changes in blood glucose, especially after meals. There are indications that these changes, for both high and low blood sugar levels, are also important for the development of late complications of Type 2 Diabetes Mellitus. Therefore, there exists a need for standardized methods which allow the monitoring of blood glucose in a more intensive way.
In this study the volunteers will receive vildagliptin (Galvus ®). Vildagliptin augments the release of insulin from your pancreas in response to a meal. Galvus ® is a government approved and registered oral drug that lowers blood glucose levels.

Study objective

Primary:
To estimate the treatment effects of vildagliptin 50 mg PO BID on 24h weighted-mean glucose (WMG), using CGM and plasma glucose, collected at the end of a two-week treatment period.

Secondary:
1) To estimate the treatment effects of vildagliptin 50 mg PO BID on various glucoregulatory parameters, including but not limited to Hemoglobin A1C and GLP-1, Glucagon and other incretins.
(2) To evaluate the relationship between circulating levels of incretins and the various glucoregulatory parameters.
(3) To evaluate the feasibility of CGM as a tool to measure glycemic control, when compared with more traditional parameters of glycemic control.

Study design

This is a fixed sequence, single-blind, placebo-controlled, multi dose study in a group of ~30 T2DM patients.

Procedures and assessments:
Pre-study and post-study screening and follow-up: clinical laboratory, physical examination, 12-lead ECG, vital signs, medical history, drug screen, HBsAg, anti HCV, anti-HIV 1/2; clinical laboratory. Follow-up will be performed by a phone call.

Observation period: an 8 week washout period, in which all blood glucose lowering medication other that metformin should be discontinued followed by 4 periods in clinic from Day -1 to Day 4.

Blood sampling:
For blood glucose, insulin and c-peptide, GLP-1, glucagon and PYY samples: On Day 16 of period 2 and 3, and Day 65 of period 4.
DPP4 samples: On Day 2 Period 1 (Baseline), Day 16 of period 2 and 3 and Day 7, 21, 35 and 65 of period 4

Safety assessments:
Adverse events: throughout the study .
Safety and tolerability: throughout the study .

Intervention

Pharmacodynamics : plasma and urine glucose concentrations, C-peptide, insulin, GLP-1/glucagon concentrations.
Pharmacokinetics : Plasma DPP-4i concentrations.
Safety : adverse events, vital signs, ECG-parameters, laboratory parameters, physical examination.

Study burden and risks

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

Adverse Events Galvus:
The most common side effect with Galvus (seen in between 1 and 10 patients in 100) is dizziness. Common: nausea.
Sometimes: weight loss, loss of appetite, abdominal pain, diarrhea, low blood sugar, drowsiness.

Contacts

Public
PRA International EDS

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NL
Scientific
PRA International EDS

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients diagnosed with DM Type 2
18-79 years, inclusive
BMI 23-38 kg/m2 inclusive
non smoker or smoke less than 5 cigarettes

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. In case of donating more than 1.5 liters (males) or 1.0 liters (females) of blood in the 10 months prior the start of this study. Participation is also not permitted when participated in more than 3 other drug studies in the 10 months prior to the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2012
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Galvus
Generic name:	Vildagliptin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-11-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-12-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-03-2012
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	EUCTR2011-005142-35-NL
CCMO	NL40159.056.12