Study to Determine Presence of Prediabetes in Subjects with Cardiovascular Disease

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This study will assess the presence of prediabetes (defined as glycated hemoglobin [HbA1c] greater or equal to 5.7% and greater or equal to 6.4%, or fasting plasma glucose [FPG] greater or equal to 100 mg/dL [5.6 mmol/L] and greater or equal to 125...

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON42994

Source
ToetsingOnline

Brief title
Prescreening Pilot

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, increased blood sugar

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen

Intervention

Keyword: Cardiovascular, Prediabetes

Outcome measures

Primary outcome

* support the assessment of the feasibility of conducting a clinical study in

this population, and

* identify subjects with CV disease and prediabetes who might have interest in

participating in a future clinical study.

Secondary outcome

/

Study description

Background summary

This study is being conducted to determine if there is sufficient presence of prediabetes at investigative sites in subjects with cardiovascular (CV) disease to warrant a future clinical study in this population.

Study objective

This study will assess the presence of prediabetes (defined as glycated hemoglobin [HbA1c] greater or equal to 5.7% and greater or equal to 6.4%, or fasting plasma glucose [FPG] greater or equal to 100 mg/dL [5.6 mmol/L] and greater or equal to 125 mg/dL [6.9 mmol/L]) in subjects who have documented symptomatic atherosclerotic CV disease and are therefore at increased risk for CV events, with the objectives to
* support the assessment of the feasibility of conducting a clinical study in this population, and
* identify subjects with CV disease and prediabetes who might have interest in participating in a future clinical study.

Study design

This is a multicenter, exploratory study. No study drug will be administered.

Up to 800 investigative sites will enroll subjects into this study. The initial duration of the enrollment period for an investigative site will be 2 months. Extensions to the enrollment period at individual sites may be granted upon request with the approval from the sponsor. The study is considered completed after the last subject enrolled completes all study procedures.
To identify potential subjects for this study, chart reviews or a medical record search will be performed. Subjects with symptomatic atherosclerotic CV disease, without a history of diabetes, and meeting the inclusion/exclusion criteria will be contacted as follows:
Group A: Subjects with HbA1c or FPG in the prediabetes range(s) within the previous 3 months documented in the medical record (excluding HbA1c or FPG values within 1 month after an acute CV event) will be contacted for their interest in participating in a future potential clinical study.
Group B: Subjects without HbA1c or FPG in the prediabetes range within the previous 3 months will be contacted. If they are interested in participating in a future potential clinical study, they will be invited for a site visit to determine whether their current HbA1c and/or FPG parameters indicate the presence of prediabetes. Subjects in Group B will have only one study visit, at which an informed consent will be signed and blood samples will be collected to assess HbA1c and FPG.

Intervention

All subjects meeting the inclusion and exclusion criteria in Group A will be contacted and asked if they are interested in participating in a future potential clinical study. If they have interest or may be interested, CV diagnoses and disease characteristics and HbA1c and/or FPG values will be recorded, as will their interest in participating in a future potential clinical study. No study procedures will be performed for Group A subjects.
All subjects meeting the inclusion and exclusion criteria in Group B will be contacted and asked if they are interested in participating in a future potential clinical study. If they have interest or may be interested, Group B subjects will be invited to come to the site for a study visit. At the Group B study visit, informed consent must be signed before any study procedures are performed. Each subject will have only 1 study visit, at which blood samples will be collected to assess HbA1c and FPG. A sample for FPG will be collected only if a subject comes to the study visit fasting (as per procedure approved by local Independent Ethics Committee or Institutional Review Board [IEC/IRB]). If the subject has not fasted before the visit, only a sample for HbA1c will be collected. Cardiovascular diagnoses and disease characteristics and HbA1c and/or FPG values will be recorded.
Investigators will be responsible for ensuring follow up of any abnormal laboratory findings according to the standard of care per local guidance.

Study burden and risks

Adverse events (serious or non-serious) that are related to the study procedure (eg, venipuncture) should be recorded in the source documents (eg, progress notes) according to Good Clinical Practice (GCP) and retained at the site. As there is no therapeutic intervention in this study, only adverse events that are serious and related to the study procedure will be reported to the sponsor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Man or woman of *18 years of age
* Documented symptomatic atherosclerotic CV disease including a history of one of the following:
* Stroke
* Myocardial infarction

* Hospitalized admission for unstable angina
* Percutaneous coronary intervention (with or without stenting)
* Peripheral revascularization (angioplasty or surgery)
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Clinical Protocol 28431754PRD0001
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Approved, Date: 29 March 2016
* Symptomatic with documented hemodynamically significant carotid or peripheral vascular disease

Exclusion criteria

* History of T2DM, type 1 diabetes mellitus, latent autoimmune diabetes in adults (LADA), diabetic
ketoacidosis
* History of hereditary glucose-galactose malabsorption or primary renal glycosuria
* History of use of a glucose lowering drug (other than short-term use during a hospitalization or for
gestational diabetes; or subjects with a history of gestational diabetes may be included if at least
3 months has passed since the discontinuation of a glucose lowering drug)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Not approved

Date:	11-10-2016
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
Other	2016-001457-41
CCMO	NL57775.072.16