Diabetes REarCh on patient sTratification (DIRECT) work package 3.2: metformin intolerance

Published: 07-06-2013
Last updated: 24-04-2024

The objective of the study is to develop a biorepository from patients with extreme metformin intolerance to assess predictive biomarkers (clinical, genetic and genomic) of intolerance.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON38746

Source
ToetsingOnline

Brief title
DIRECT metformin intolerance

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Diabetic complications

Synonym
Type 2 Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Door de Europese Unie gefinancierd IMI-DIRECT-consortium

Intervention

Keyword: intolerance, metformin, type 2 diabetes

Outcome measures

Primary outcome

First a biorepository containing genetic profiles, biochemical and clinical characteristics of the patients will be constructed. This biorepository will be used to identify predictive biomarkers (clinical, genetic and genomic) of metformin intolerance.

Secondary outcome

Not applicable.

Study description

Background summary

There is considerable variability in who gets gastrointestinal side effects with metformin treatment. About one quarter of patients experience gastrointestinal side effects that are mild or self-limiting, but 1 in 20 have such severe side effects that they are unable to tolerate any dose or just a low dose (500mg). The aim of this study is to collect a cohort of patients who have such extreme intolerance and identify predictive genetic and metabolic biomarkers for intolerance. This study is part of a wider study taking place in our centre and other centres in the UK, Denmark, Sweden and Germany as part of the European union-funded IMI-DIRECT consortium. DNA, serum, plasma and urine will be pseudonymized and collected in a biorepository for comparison with a group of metformin tolerant patients (prescribed >= 2g metformin for more than 6 months) from the same centre who are participating in another study and from centres within the DIRECT consortium.

Study objective

The objective of the study is to develop a biorepository from patients with extreme metformin intolerance to assess predictive biomarkers (clinical, genetic and genomic) of intolerance.

Study design

Observational cohort study

Study burden and risks

Before the annual check-up at the DCS screening questions will be sent to the participants or asked by phone to confirm severe metformin intolerance in the past, informed consent to use data from medical records and the donation of blood and urine will be taken. A donation of a blood sample (30 ml) and one urine sample (5 ml) will be asked of the subjects. Because this will be done during one of the regular visits, the risk as well as the burden for the subjects is negligible. The donated blood and urine samples will be pseudo-anonymized, collected in a biorepository and analysed (e.g. DNA profiling and metabolomics) when the cohort is complete. Benefit for the subjects will be the identification of risk factors for metformin intolerance, which may facilitate the development of better treatment.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent
Patients with Type 2 diabetes
White European
Potential metformin intolerance

Exclusion criteria

- Type 1 diabetes
- Age at study start <18 or >90
- Inability to consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	07-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL43631.029.13