Add-on study of new biomarkers in Type 2 Diabetes Mellitus

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20896

Source
Nationaal Trial Register

Health condition

Type 2 Diabetes Mellitus, wash-out and restart of metformin, explorative biomarkers of inflammation

Sponsors and support

Primary sponsor: no sponsor
Source(s) of monetary or material Support: self-financing research in cooperation with TNO Quality of Life, TNO Metabolic Health Research, Leiden

Intervention

Outcome measures

Primary outcome

N/A

Secondary outcome

N/A

Study description

Background summary

PILOT TRIAL IN TYPE 2 DIABETES MELLITUS PATIENTS TO EXPLORE NEW FINGERPRINTS AND FUNCTIONAL MARKERS DURING START AND STOP OF REGULAR PHARMACOLOGICAL GLUCOSE LOWERING TREATMENT AS ADD-ON TO NEW COMPOUND PHASE 1 STUDIES

Objectives

Primary: To examine the effects of regular glucose lowering treatment on inflammatory markers in type 2 Diabetes Mellitus

Secondary: To identify markers/fingerprints that predict the response of a patient to glucose lowering therapy in type 2 Diabetes Mellitus

To identify fingerprints/markers related to pathogenic mechanisms of type 2 Diabetes Mellitus

Methodology
Design:Non interventional study in which only blood and urine samples will be collected. (add-on procedures on top of new compound phase 1 studies, only for patients)

Procedures and assessments

Blood and urine sampling: Fasting blood and urine samples before and after wash-out and before restart and at follow-up of regular glucose lowering medication. Sample timing as per the main study visit schedule. For exploratory markers: samples of blood and urine before and after wash-out period and before and after restart regular glucose lowering medication

Assessments: No assessments. Patient data which is already collected during screening, wash-out and restart periods in a new compound phase 1 study will be used (copy of data)

Bio analysis: Paired (before/after) analysis of samples using an established method. The analyses will include a) a panel of (tissue-specific) functional markers which are determined by ELISA or multiplex analyses to assess the metabolic and inflammatory state of the entire organism as well as of specific organs (tissue-specific functional markers), b) metabolomics/lipidomics (analysis of specific lipids, metabolites, peptides) and c) a targeted analysis of miRNAs associated with cardiometabolic disease.

Diagnosis and main criteria for inclusion

Criteria: Diabetes Mellitus type 2 patients eligible to start wash-out as per criteria in new compound studies

Pathology: Type 2 Diabetes Mellitus

Patients: Patients who are selected to participate in a new compound phase 1 study and who are willing to give their consent for this add-on study (minimum n=30)

Criteria for evaluation

Pharmacodynamics: changes in concentration from baseline of known and exploratory markers of regular glucose lowering medication

Markers: Biomarkers to be used for evaluation of tissue-specific markers of inflammation include:

- Liver-related: Fibrinogen,CRP, SAA, IL-10, specific miRNAs (e.g. miRNA34a), DNA, mRNA, betatrophin

- Adipose tissue related: Adipokines such as leptin, adiponectin, resistin, PAI-1, MCP-1, betatrophin

- Muscle related: Myokines, irisin, branched chain amino acids

- Vasculature/ Endothelial dysfunction : VCAM, ICAM, vWF, E-selectin,

- Pancreas: insulin, C-peptide, glucagon

- Lipid-mediators and metabolites associated with metabolic imbalance and inflammation among which bioactive lipids, phospholipids, amino acids, peptides, carbohydrates, nucleotides, hormones, T1AM, carnitine and derivates, vitamins) . These analytes will be determined (semi-quantitatively) by an established combined lipidomics and metabolomics platform.

Statistical methods

PD parameters: explorative descriptive statistics.

Study objective

Objectives

Primary: To examine the effects of regular glucose lowering treatment on inflammatory markers in type 2 Diabetes Mellitus

Secondary: To identify markers/fingerprints that predict the response of a patient to glucose lowering therapy in type 2 Diabetes Mellitus and To identify fingerprints/markers related to pathogenic mechanisms of type 2 Diabetes Mellitus

Study design

4 time points: Fasting blood and urine samples before and after wash-out and before restart and at follow-up of regular glucose lowering medication. Sample timing as per the main study visit schedule. For exploratory markers: samples of blood and urine before and after wash-out period and before and after restart regular glucose lowering medication

Intervention

Non interventional study in which only blood and urine samples will be collected. (add-on procedures on top of new compound phase 1 studies, only for patients).

Contacts

Public
PRA
Early Development Services
Stationsweg 163

R.G. Tiessen
Zuidlaren 9471 GP
The Netherlands
(31)-50-402 2386
Scientific
PRA
Early Development Services
Stationsweg 163

R.G. Tiessen
Zuidlaren 9471 GP
The Netherlands
(31)-50-402 2386

Eligibility criteria

Inclusion criteria

Diabetes Mellitus type 2 patients eligible to start wash-out as per criteria in new compound studies

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-07-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-06-2013
Application type:	First submission

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
NTR-new	NL3857
NTR-old	NTR4018
Other	PRACLINI : 131461
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A