Metformin dosing related to renal clearance in outpatients: The MetClear study

Published: 05-10-2009
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Is the metformin dose correctly adjusted to the renal clearance of the individual DM2 patient? Is there a correlation between high metformin concentrations and biochemical parameters e.g. lactic acid in the blood?

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

Summary

ID

NL-OMON35525

Source
ToetsingOnline

Brief title
The MetClear study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus type II

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lactate, metformin, renal clearance

Outcome measures

Primary outcome

To gain a better insight in metformin dose and adjustments to renal clearance.

Secondary outcome

Correlation between metformin dose, renal clearance (MDRD), metformin and

lactic acid concentration in blood.

Study description

Background summary

For therapeutic treatment of diabetic patients, metformin is the preferent drug to prescribe according to the NHG standard and international guidelines. Hence metformin prescriptions have increased. According to dosing guidelines metformin dose should be adjusted in case of a decrease in renal clearance (MDRD). It is still unclear if not acting in concordance to the dosing guidelines will lead to increased metformin concentrations. It has been reported that a relative high concentration of metformin in the blood may cause a lactic acidosis. To our knowledge there is no consensus on the correlation between metformin and lactate concentrations.

Study objective

Is the metformin dose correctly adjusted to the renal clearance of the individual DM2 patient? Is there a correlation between high metformin concentrations and biochemical parameters e.g. lactic acid in the blood?

Study design

Prospective pilot study, in which 90 patients will enrole. These patients will be assigned according to renal clearance (MDRD) following the matrix of the study protocol (see below).

MDRD Metformine Bioch. Parameters HbA1c Bijwerkingen Comorbiditeit dosering serum lactaat

(ml/min) (mg) (mmol/L)

0 - 30

30 - 60

> 60

Study burden and risks

The blood samples required for this study will be obtained by trained medical staff during routine clinical check up. Therefore no extra burden or risk is involved for the patients.

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

diagnosis of diabetes mellitus type II, treatment with metformin

Exclusion criteria

no diabetes mellitus type II, treatment without metformin, participation in other study with blinded study drug

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2009
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-06-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-12-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL28316.098.09