Regulation of prothrombotic factors in blood of type II diabetes mellitus patients

Published: 15-01-2008
Last updated: 10-08-2024

The objectives of this study are to gain new insights on [1] the cause of a higher clopidogrel resistance in DMII patients[2] the increased production of tissue factor in monocytes in DMII patients

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	Observational invasive

Summary

ID

NL-OMON35350

Source
ToetsingOnline

Brief title
Clopi2007

Condition

- Platelet disorders
- Diabetic complications

Synonym
diabetes mellitus / diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: clopidogrel, diabetes mellitus, monocyt, platelets

Outcome measures

Primary outcome

Part 1 (study on platelets)

[1] Is it possible to identify clopidogrel resistant patients by aggregation studies?

[2] Is it possible to explain this resistance by a difference in one of the components in the P2Y12 signalling cascade?

[3] Why does insulin resistance leads to differences in P2Y12 signalling?

Part 2 (study on monocytes)

[1] Do monocytes of DMII patients have a normal inhibiton of tissue factor production by insulin?

[2] What is the cause of insulin resistance in DMII monocytes?

[3] Is the P2X7 receptor a possible target for interference of tissue factor production?

Secondary outcome

N/A

Study description

Background summary

Patients with diabetes have a absolute or relative defect in insulin functioning or secretion. They have a higher risk of developing cardiovasculair

diseases compared to healthy individuals. Besides changes in the vessel wall these patients appear to have hyperactive platelets and an increased activitity of the coagulation cascade. The platelets and monocytes (the source of tissue factor, the protein responsible for the start of coagulation) become activated after an in healthy persons not activating stimulus and can cause pathological vessel occlusions. Also, the platelets of type II diabetes (DMII) patients are more resistant against the aggregation inhibiting activity of clopidogrel than their healthy counterparts. This so-called clopidogrel resistance is associated with a higher chance of atherothrombosis.

Study objective

The objectives of this study are to gain new insights on
[1] the cause of a higher clopidogrel resistance in DMII patients
[2] the increased production of tissue factor in monocytes in DMII patients

Study design

Observational study

Study burden and risks

Blood (60 ml) is withdrawn from participating subjects only once. Several experiments can be done with this blood. Besides the fact that subjects can't have breakfast before the punction, the load and risks for participants are minimal.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

[1] matched controls
[2] DMII patients taking insulin
[3] DMII patients taking insulin and clopidogrel
[4] DMII patients taking oral bloodglucose lowering drugs (biguanides or sulfonylurea derivatives)
[5] DMII patients taking oral bloodglucose lowering drugs (biguanides or sulfonylurea derivatives) and clopidogrel

Exclusion criteria

Pregnancy
Use of anti-epileptic drugs
Use of acetyl salicylic acid or other non-steroidal anti-inflammatory drugs

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL19880.041.07