Inhibition of platelet activation by clopidogrel in type II diabetes mellitus patients

Published: 15-07-2008
Last updated: 10-08-2024

The objective of the study is to gain new insights in the causes of a higher clopidogrel resistence in type II diabetes mellitus patients

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

Summary

ID

NL-OMON32343

Source
ToetsingOnline

Brief title
clopi2008

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, platelets

Outcome measures

Primary outcome

[1] ADP and collagen stimulated Ca2+ mobilization of platelets

[2] ADP and collagen stimulated P-selectin expression on platelets

Secondary outcome

NVT

Study description

Background summary

Diabetes mellitus patients suffer from an absolute or relative defect in insulin function or secretion. They have an increased risk on the development of cardiovascular diseases compared to healthy persons. Besides changes in the vascular wall, they also have hypersensitive platelets, leading to pathologic vessel occlusions, after a small stimulus. The platelets of type II diabetes mellitus patients are more resistent to clopidogrel than non diabetic patients. This is associated with atherothrombotic events.

Study objective

The objective of the study is to gain new insights in the causes of a higher clopidogrel resistence in type II diabetes mellitus patients

Study design

Observation study

Intervention

clopidogrel 75 mg per dag for one week

Study burden and risks

60 ml of blood is withdrawn from participating persons twice. Between the first and second blood withdrawal the subjects take clopidogrel for one week. Clopidogrel can cause side-effects. With this blood two platelet functional assays are performed, which can contribute to the knowledge on clopidogrel resistence in type II diabetes mellitus.

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

1. healthy controls (matched by age and gender)
2. type II DM patients, treated with oral bloodglucose lowering agents (biguanides or sulfonylurea derivates)

Exclusion criteria

pregnancy; use of anti-epileptic drugs; use of acetylsalicylacid, NSAID, GPIIb-IIa antagonists, heparin or thrombolytica; known diabetic retinopathy; smoking; hypersensitivity to the drug substance or any component of the product; severe liverfunctiondisorder; active pathological bleeding such as peptic ulcer or intracranial hemorrhage; breastfeeding; surgery or dental operation 7 days prior or 7 days after the start of clopidogrel intake; galactose intolerance, lapp lactase deficiency or glucose galactose malabsorbtion

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2009
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	plavix
Generic name:	clopidogrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-07-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-10-2008
Application type:	First submission
Review commission:	METC NedMec

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
EudraCT	EUCTR2008-004147-11-NL
CCMO	NL23416.041.08