Het Siemens INNOVANCE* PFA P2Y Test Cartridge Project

Published: 01-10-2009
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Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33130

Source
ToetsingOnline

Brief title
Het Siemens INNOVANCE* PFA P2Y Test Cartridge Project

Condition

- Coronary artery disorders

Synonym
Coronary artery disease - atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Siemens Healthcare Diagnostics
Source(s) of monetary or material Support: Siemens Healthcare Diagnostics

Intervention

Keyword: clopidogrel, platelet function test, Platelets

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Study burden and risks

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Contacts

Public
Siemens Healthcare Diagnostics

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Duitsland
Scientific
Siemens Healthcare Diagnostics

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients must have a history of vascular disease (cardiovascular or cerebrovascular) or at least two of eight risk factors for developing vascular disease based on the following American Heart Association criteria:
• current or previous history of smoking
• hypertension
• hyperlipidemia
• family history of vascular disease
• post-menopausal females
• diabetes mellitus
• morbid obesity
• sedentary lifestyle
Other inclusion criteria
• >=18 years of age (18 to 90)
• Documented history of vascular disease (cardiovascular or cerebrovascular) or at least two of the risk factors for developing vascular disease described in §3.1
• Eligible to receive clopidogrel
• Indication for clopidogrel
• Able to provide written, informed consent in accordance with the IRB (internal review board or ethics committee) and agree to comply with all protocol-specified procedures

Exclusion criteria

• <18 years of age
• Treatment with any drug inhibiting platelet function, such as GPIIb/IIIa inhibitors, ticlopidine or dipyridamole, but not acetylsalicylic acid (Aspirin®) or clopidogrel

• Known inherited or acquired platelet function disorder
• Known inherited or acquired von Willebrand disease
• Pathological CT with PFA ADP Cartridge (3.2% citrate) before intake of clopidogrel
• Current participation in another trial with a substance known to affect platelet function or any investigational new drug
• Platelet count < 150 x109/L to avoid interferences for LTA

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	01-10-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL29319.100.09