IMPACT:
Does the absolute magnitude of Platelet Inhibition inversely correlates with the number of TCD-detected microemboli during and after CAS in asymptomatic patients undergoing carotid artery stenting prior to cardiac surgery who are being pre-treated with either a 300 mg or a 600 mg loading dose of clopidogrel?

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Firstly, to investigate whether the absolute magnitude of Platelet Inhibition inversely correlates with the number of TCD-detected microemboli during and after CAS in patients who are being pre-treated with either a 300 mg or a 600 mg loading dose...

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON31555

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
carodit stenosis

Research involving
Human

Sponsors and support

Primary sponsor: R&D Cardiologie
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott Vascular

Intervention

Keyword: carotid artery stenosis, microemboli, plavix, transcranial doppler

Outcome measures

Primary outcome

The number of TCD-detected microemboli during a 60 minutes monitoring period

immediately after the CAS procedure.

The absolute level of platelet inhibition after pre-treatment

Secondary outcome

The cerebral complications in the first 30 days following the procedure.

Study description

Background summary

As with coronary artery stenting, activation and embolisation of platelets occurs with carotid artery stenting(CAS). Based on promising data on the use of clopidogrel plus aspirin in coronary stenting this dual antiplatelet regimen has been introduced as adjunctive treatment during CAS. There is as yet, however, no randomized controlled trial which compared different loading doses of clopidogrel during CAS. Taking into account that a wide interindividual

variability in the response to a loading of clopidogrel exists, this study is intended to establish the optimal loading dose of clopidogrel. Therefore platelet function testing and a 1-hour of postprocedural TCD (transcranial doppler) monitoring will be performed.

Study objective

Firstly, to investigate whether the absolute magnitude of Platelet Inhibition inversely correlates with the number of TCD-detected microemboli during and after CAS in patients who are being pre-treated with either a 300 mg or a 600 mg loading dose of clopidogrel. Secondly, if there is any impact on early neurological outcome determined by the loading dose of clopidogrel.

Study design

This is prospective, double-blinded, randomized, single center study.

Intervention

All patients will receive a loading dose of 600mg of study medication. The first group will receive 300 mg of clopidogrel and 300 mg placebo, the second group will receive 600mg of clopidogrel

Study burden and risks

For the group of patients receiving a loading dose of 600 mg clopidogrel, one could assume that bleeding complications are higher than in the group receiving standard 300 mg clopidogrel however this has not been described in previous conducted trials examining safety of both loading doses during coronary intervention. Therefore, it is very likely that the patient is not exposed to a higher risk when participating in this trial. Venous blood samples, necessary for measurement of platelet-inhibition will be taken together with standard blood samples before and after procedure without imposing extra venous puncture

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

-patient > 18 years of age
-patient accepted for CABG and CAS
-temporal window for TCD available

Exclusion criteria

-severe renal impairment, abnormal liver function, malignancy, febrile disorder, acute or chronic inflammatory disease and other diseases influencing platelet reactivity
-extreme tortuositas or calcification of the lesion
-patients with active bleeding or at high-risk of bleeding
-uncontrolled hypertension (> 180/110 mmHg)despite optimal medication

Study design

Design

Study phase:	2
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	90
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-06-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-10-2008
Application type:	Amendment
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
EudraCT	EUCTR2006-006129-13-NL
CCMO	NL15942.100.06