The effects of aspirin on the platelet function of healty volunteers and of patients with occlusive arterial vascular disease.

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

Summary

ID

NL-OMON31793

Source
ToetsingOnline

Brief title
EAP

Condition

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

Synonym
aspirin non-responders, aspirin resistance

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aspirinresistance, platelet function, thromboxane, volunteers

Outcome measures

Primary outcome

thromboxane B2

optical aggregometry

PFA closure time

trombinegeneration measurement in Platelet Rich Plasma

impedance aggregometry in whole blood

Secondary outcome

not applicable

Study description

Background summary

Aspirin inhibits platelet aggregation through an irreversible and competitive binding with the enzyme cyclo-oxygenase (COX). Cyclooxygenase is required for thromboxane synthesis, which is a strong vasoconstrictor and platelet triggerer. Through these mechanisms the use aspirin in patients with cardiovascular disease leads to a significant risk reduction. However, not all patients seem to benefit from the use of aspirin. An important part of the patients seem to have high platelet activity despite the use of aspirin. This is also called laboratory aspirin resistance, which can be identified by the use of several platelet function tests. Previous studies have shown that in cardiology patients with laboratory aspirin resistance, there is an increased cardiovascular risk. In case of ischemic stroke, this correlation isn't proven yet.

Study objective

Objective of the study is to investigate the effects of aspirin on the platelet function of healthy volunteers and of patients with ischemic stroke. In another part of the study, we will investigate whether or not the effects of aspirin on the platelets of patients without recurrent disease differs from the effects of patients with recurrent disease despite the use of aspirin. Next to standard platelet function tests we will also include the thrombinegeneration measurement.

Study design

It is an intervention study with 12 healty volunteers. They have to take carbasalate calcium 100mg daily during 7 days. On day 0 and dag 6 of the study, subjects have to come to the hospital, where bloods will be drawn before and after the ingestion of carbasalate calcium in order to study the effects of carbasatale calcium of the platelet function.
Another part of the study will be a pilot study with 24 patients with an ischemic stroke based on large vessel disease in the medical history. The event must have taken place between 01-07-01 and 01-07-06. All patients are treated with carbasalate calcium 100mg daily. 12 of the 24 patients have recurrent disease despite carbasalate calcium and 12 of the 24 patients don't have recurrent disease. Patients have to come to the hospital once: bloods will be drawn before and after the ingestion of carbasalate calcium in order to investigate the effects of carbasalate calcium on the platelet function.

Intervention

population A
100 mg of carbasalate calcium daily, during a period of 7 days
2x2 venapuntions

Population B
2 venapunctions
no additional medical treatment

Study burden and risks

Population A
The subjects will be treated with carbasalate calium 100mg daily during a period fof 7 days. The risk is minimal and equal to the risks of the use of carbasalate calcium. In order to minimalise the risks we will exclude volunteers with any knows (relative) contra-indication for aspirin.
The subjects will have to come to the hospital on day 0. In addition, blood will be obtained by 2 times a venapuntion (once before and once 2.5 hours after the intake of carbasalate calcium 100mg). The same procedure will be repeated

on day 6.

Population B
Patients from population B are already treated with carbasalate calcium 100mg daily. The medical treatment will remain the same during and after the study. These subjects will have to come to the hospital once. In addition blood will be obtained by 2 times a venapunction (once before and once after the intake of carbasalate calcium).

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

population A: healthy, BMI <27.5, non smoker.
Population B1: stroke in medical history (large vessel disease) between 01-07-01 and

01-07-06. No- recurrent stroke. Therapie with carbasalate calcium 100mg daily.
Population B2: recurrent stroke in medical history despite therapy with carbasalate calcium 100mg daily. First stroke between 01-07-01 and 01-07-06. last stoke > 3 months ago.

Exclusion criteria

Population A: any contra-indication for carbasalate calcium. The use of NSAIDs. Cardiovascular disease, Diabetes Mellitus. recent operation (3 months)
Population B: therapy with clopidogrel, NSAIDs, oral anticoagulation therapy. Known malignancy, operation < 3 months ago. Cardiovascular event < 3 months ago. Known hematologic disease. Thrombocytopenia(< 100000/mm3), thrombocytosis (> 400 000/mm3), anemia, polycytemia (Ht>50%)

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2007
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ascal
Generic name:	carbasalate calcium

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-08-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-10-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-12-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-04-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-05-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2007-004354-90-NL
CCMO	NL19043.068.07