

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Central nervous system vascular disorders
<b>Study type</b>	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 thrombin generation measurement.

## Study design

It is an intervention study with 12 healthy volunteers. They have to take carbasalate calcium 100mg daily during 7 days. On day 0 and day 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 carbasalate calcium on 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 venapunctures

Population B

2 venapunctures

no additional medical treatment

## Study burden and risks

Population A

The subjects will be treated with carbasalate calcium 100mg daily during a period of 7 days. The risk is minimal and equal to the risks of the use of carbasalate calcium. In order to minimise the risks we will exclude volunteers with any known (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 venapuncture (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

#### Public

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#### Scientific

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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 stroke > 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/mm<sup>3</sup>), thrombocytosis (> 400 000/mm<sup>3</sup>), anemia, polycythemia (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