Advanced glycation end products in patients with peripheral artery disease or abdominal aortic aneurysms

Published: 10-07-2015
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON45188

Source
ToetsingOnline

Brief title
ARTERY study

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral artery disease - atherosclerosis of the leg

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Mogelijk

Diabetesfonds Nederland

Intervention

Keyword: Abdominal aortic aneurysm (AAA), Advanced glycation end product (AGEs), Diabetes mellitus (DM), peripheral artery disease (PAD)

Outcome measures

Primary outcome

The primary objective is to compare the amount, type and localisation of AGEs

of the arterial wall of PAD, AAA and PAD+AAA between patients with and without

diabetes mellitus.

Secondary outcome

The secondary objectives are to explore the association between AGEs content of

the arterial wall of PAD, AAA and PAD+AAA patients and (1) serum, urine and

skin AGEs, (2) in vivo and in vitro mechanical properties of the arterial wall

and (3) serum, urine and tissue markers of inflammation and oxidative stress.

Study description

Background summary

Peripheral artery disease (PAD) and abdominal aortic aneurysms (AAA) are often simultaneously found in patients although these conditions have different pathophysiology. PAD and AAA share smoking as major risk factor. However, diabetes mellitus is a risk factor for occlusive vascular disease and protective effect in dilating disease. Accumulation of advanced glycation end products (AGEs) in the arterial wall could possibly explain the different effects of diabetes mellitus on these diseases. AGEs are sugar modified proteins which are formed under influence of oxidative and glycemic stress. AGEs have the potential to form cross-links and to induce inflammatory and oxidative stress responses after binding to the receptor for AGE. Increased accumulation of AGEs is associated with elevated risk of cardiovascular morbidity and mortality in several diseases.

Study objective

The primary objective is to compare the amount, type and localisation of AGEs of the arterial wall of PAD, AAA and PAD+AAA in patients with and without diabetes mellitus.
The secondary objectives are to explore the association between AGEs content of the arterial wall of PAD, AAA and AAA+PAD patients and (1) serum, urine and skin AGEs, (2) in vivo and in vitro mechanical properties of the arterial wall and (3) serum, urine and tissue markers of inflammation and oxidative stress.

Study design

Multicenter observational cross-sectional study design.

Study burden and risks

Patients do not have benefit in this study. Patients have to fill in a questionnaire about cardiovascular risk factors, one additional visit is necessary to the hospital for noninvasive vascular measurements (3 hours) and 60 ml blood will be drawn by venipuncture. For the vascular measurements and the blood tests, the patients will be asked to fast at least 8 hours before the tests. On the day before the additional hospital visit, 24h urine will be collected. During surgery, a noninvasive echo graphic measurement will be performed and waste material of the arterial wall will be collected. The measurements during surgery prolong surgery time with a maximum of 10 minutes.

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

Age above 18 years old.
Written informed consent for study participation.
Proven PAD or AAA
PAD: patients planned for a bypass surgery or endarterectomy of the lower arteries, and/or:
AAA: patients planned for an open repair of the aneurysm.

Exclusion criteria

Patients not able or willing to sign informed consent.
rheumatoid arthritis, systemic lupus erythematosus, Giant Cell Arteritis, retroperitoneal fibrosis, Takayasu arteritis or any other systemic inflammatory disorder.
Patients with Ehlers-Danlos syndrom or Marfan syndrom
Patients with signs of an inflammatory or mycotic aneurysm (on computed tomographic angiography).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2016
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	10-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29072
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45660.042.14
OMON	NL-OMON29072