ISRCTN03932642 https://doi.org/10.1186/ISRCTN03932642

The association between the 5-LipOxygenase pathway and abdominal aortic aneurysms

Submission date	Recruitment status	[_] Prospectively registered
28/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2021	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr L N Broekhuizen

Contact details
Academic Medical Center (AMC) Amsterdam
Department of Vascular Medicine, F4-142
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
-
L.N.Broekhuizen@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL770, NTR781

Study information

Scientific Title
The association between the 5-LipOxygenase pathway and abdominal aortic aneurysms

Acronym
5-LO pathway

Study objectives
Rationale: Accumulating evidence suggests that increased generation of LeukoTrienes (LT) by the 5-LipOxygenase (5-LO) pathway may have direct actions on the vessel wall, particularly the adventitia, in the evolution of Abdominal Aortic Aneurysm (AAA). Augmented inflammatory activity may further weaken the arterial wall, which may result in rapid expansion of the AAA and ultimately rupture. Thus, circulating and/or urinary levels of LT may serve as a novel biomarker for monitoring small asymptomatic AAA and may be an useful predictor of aneurysmal expansion.

We hypothesise that:
1. LTs produced by the 5-LO pathway are adversely implicated in the progression of AAA, and
2. Certain 5-LO pathway associated haplotypes (e.g. spanning the LT4h gene or FLAP) may be associated with rapid expansion of AAA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the medical ethics commission of the Academic Medical Centre on November 2, 2006 (ref: MEC 06/240).

Study design
Non-randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Abdominal aneurysm of the aorta

Interventions

Patients with an asymptomatic, small aneurysm of the abdominal aorta and healthy male volunteers will visit the hospital four times during two years, at an interval of six months. During the first visit, patients will undergo a short physical examination, blood sampling, and ultrasound scanning for measurement of the maximum anterior-posterior diameter of the abdominal aorta.

During the follow up visits patients will be subjected only to ultrasound scanning. Except for blood sampling related inconvenience (e.g., hematomas) there are no risks associated with participation. In addition, there are no direct benefits for subjects participating in this study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The relation between LT levels (in stimulated neutrophils and urine) and annual rate of expansion of small AAAs.
2. Comparison of LT levels between subjects with AAA and normal controls.
3. The association between at-risk gene variant genes involved in 5-LO pathway and AAA growth rate.
4. To assess the presence of neutrophils and 5-LO products in AAA specimens.

Secondary outcome measures
The relation between other inflammatory markers (e.g. MMP9, hsCRP, MIP-1a, RANTES, MCP-1, CD-40L) and rates of expansion of small AAAs.

Overall study start date
01/11/2006

Completion date
01/11/2009

Eligibility

Key inclusion criteria
1. Presence of asymptomatic, small AAA
2. Older than 20 years
3. Male or female

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants

200

Key exclusion criteria
1. A clinical condition which is actual and may interfere with the endpoints of the study (e.g. malignancy, infection/sepsis, chronic inflammatory disease)
2. The use of drugs with anti-inflammatory properties including prostaglandin synthetase inhibitors, which have been shown to reduce the inflammatory response
3. The use of immunosuppressants, including glucocorticoids, e.g., cyclosporine
4. Ruptured/symptomatic AAAs

Date of first enrolment
01/11/2006

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC) Amsterdam
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
Department of Vascular Medicine
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Other

Funder Name
This study was funded by the principal investigator of this trial, and received no external funding.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	genetic analysis results	01/02/2012	14/01/2021	Yes	No