MRI molecular imaging of (inflammatory) macrophages as a predictor of abdominal aortic aneurysm progression

Published: 23-07-2008
Last updated: 06-05-2024

I. The main objective of our study is to differentiate between patients with stable or slowly growing AAA from patients with rapidly growing AAA. We believe that inflammation is a major player in the process of growth. In order to achieve our main...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON32371

Source
ToetsingOnline

Brief title
Imaging of inflammation in AAA

Condition

- Aneurysms and artery dissections

Synonym
AAA, Aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Lopende aanvraag bij Nederlandse Hartstichting

Intervention

Keyword: Abdominal aortic aneurysm, inflammation, molecular imaging, MRI

Outcome measures

Primary outcome

The main study parameter is the change in relative decrease of the post USPIO MR signal between different follow up moments. This relative signal loss will be related to the maximal aortic diameter change between different follow up moments.

The main objective of our study is to differentiate between patients with stable or slowly growing AAA from

patients with rapidly growing AAA. We believe that inflammation is a major player in the process of growth. In order to achieve our main objective we need to relate the individual degree and distribution of the inflammation of the AAA wall to specific growth rate and patterns. Inflammation will be visualized by means of USPIO-enhanced MR.

Secondary outcome

Secondary objectives are to associate the degree and distribution of the inflammation of the abdominal aortic

wall of patients with AAA with (i) systemic markers of inflammation, and (ii) the distribution of the wall stress.

Study description

Background summary

A prominent histological feature of abdominal aortic aneurysm (AAA) is the transmural infiltration of macrophages and lymphocytes. Inflammation of the aortic wall and the progression of AAA are closely related. Early identification of inflammation could aid in the identification of a subset of AAA patients in need of close monitoring and medical therapy. Conversely, patients with little inflammation (stable AAA) could be spared from either medical or surgical treatment, till later date.
Based on our experience with USPIO enhanced MR, AAA wall stress analysis and the knowledge of AAA wall components we hypothesize that: I. The degree and distribution of the inflammation of the abdominal aortic wall in patients with AAA is - as visualized with USPIO-enhanced MR - related to AAA progression. II. The degree of the inflammation of the abdominal aortic wall of patients with AAA is related to systemic inflammatory markers in peripheral blood. III Based on the USPIO enhanced MR and or systemic inflammatory markers we will be able to differentiate patients with stable or slowly growing AAA from patients with rapidly progressive AAA. IV. The distribution of the inflammation is related to the distribution of the wall stress.

Study objective

I. The main objective of our study is to differentiate between patients with stable or slowly growing AAA from patients with rapidly growing AAA. We believe that inflammation is a major player in the process of growth. In order to achieve our main objective we need to relate the individual degree and distribution of the inflammation of the AAA wall to specific growth rate and patterns. Inflammation will be visualized by means of USPIO-enhanced MR. II. Secondary objectives are to associate the degree and distribution of the inflammation of the abdominal aortic wall of patients with AAA with (i) systemic markers of inflammation, and (ii) the distribution of the wall stress.

Study design

Observational follow-up study

Study burden and risks

The timescale of our protocol is identical to the normal follow up regimen of patients with small AAA. The exposure of these patients to bi-annual CTA imaging is considered safe with regards to the exposure to radiation. The contrast medium (Iodine) used is routinely used and has been shown to rarely generate anaphylactic response and/or shock. Mild symptoms are seen in less than 1% of all cases and severe symptoms are rare. The use of a 64-slice machine ensures minimal contrast dosage. Patients with severe renal dysfunction will be excluded (eGFR < 30). With regards to the USPIO, we are fortunate to have the experience of the team members of the department of Radiology with the USPIO (Sinerem®, Guerbet, Paris). No adverse events were observed in the

carotid artery plaque study. Sinerem is well-tolerated in human subjects and has minimal side-effects. The preclinical pharmacokinetic and safety profile of ferumoxtran-10 appears to be satisfactory in view of its proposed use as a single-dose diagnostic agent in human for MR imaging of lymph nodes. (Bourrinet et al. Invest Radiol. 2006 Mar;41(3):313-24.)

Contacts

Public
Academisch Ziekenhuis Maastricht

P. Debyelaan 25
6202AZ Maastricht
NL
Scientific
Academisch Ziekenhuis Maastricht

P. Debyelaan 25
6202AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For phase 1: all patients with an AAA which are eligable for surgical repair. For phase 2: all patients with an AAA with a diameter between 30 and 50 mm which are under surveillance at our hospital.

Exclusion criteria

Patients with clinical inflammatory AAA and/or other inflammatory disorders. Patients with contraindications for MR scanning, including a pacemaker, metal objects in the eye, middle ear implants, implanted pumps or neurostimulators. And relative contraindications for MR scanning: metal cardiac valve, intracranial clips/coils for aneurysm, vena cava filter and metal prosthesis. Patients with contraindication for contrast enhanced CT, including those with a previous anaphylactic response to the contrast medium and patients with diminished kidney function as reflected by a serum creatinine of >130 µmol/l.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2008
Application type:	First submission
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
Other	3631
CCMO	NL23487.068.08