The effect of Telmisartan on inflammatory processes in the vascular wall of abdominal aortic aneurysms.

Published: 26-10-2015
Last updated: 19-04-2024

In this study we would like to study the effects of the selective angiotensin II antagonist Telmisartan on inflammation and cell/matrix homeostasis in the human aneurysm aortic wall.

Ethical review	Approved WMO
Status	Pending
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON43688

Source
ToetsingOnline

Brief title
TELMI

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm. aneurysm.

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Australian National Health and Medical Research Council;projectgebonden subsidie

Intervention

Keyword: Abdominal aortic aneurysm, Medical Management, Telmisartan

Outcome measures

Primary outcome

Exploratory pathway analysis of markers for inflammation, cell proliferation

and matrix remodeling.

Secondary outcome

n.a.

Study description

Background summary

An abdominal aortic aneurysm is a balloon-shaped dilatation of the lower part of the largest artery of the human body. An aneurysm gives almost no symptoms, but the danger of an aneurysm is the potential risk of sudden tearing. This leads to an life-threatening bleeding. Aneurysm rupture leads to an estimate of 800 deaths per year in the Netherlands and aneurysm treatment costs up to 50 million euro's per year. Causing aneurysm's to be an considerable health issue.

The chance of rupture is very small in smaller aneurysms however the chance increases fast with larger diameters. There is a great need for medical inhibition of aneurysm growth, since this will lead to fewer aneurysm surgery's. Animal studies showed that angiotensin II antagonists can inhibit aneurysm growth and development. In this observational intervention study we would like to explore the effects of the angiotensin II antagonist Telmisartan on inflammation in the human aneurysm wall. This study will run parallel to the currently running study P12.094 "TEDY: Telmisartan in the management of abdominal aortic aneurysm.", with number NL40515.058.12, in which the potential clinical effect of Telmisartan on AAA growth is under evaluation.

Study objective

In this study we would like to study the effects of the selective angiotensin II antagonist Telmisartan on inflammation and cell/matrix homeostasis in the human aneurysm aortic wall.

Study design

An observational intervention study in which 15 patients who are planned to have elective aneurysm repair are requested to take a daily dose of 40 mg Telmisartan 2 to 4 weeks prior to surgery. During surgery aneurysm tissue will be collected and preserved. This does not extend the impact of the surgery nor does it alter the recovery/care afterwards. The collected tissue samples will then be analysed for markers for inflammation, cell proliferation and matrix remodeling. Results will be compared to tissue samples from patients who have been treated with an ACE inhibitor preoperatively and tissue for patients who didn't receive preoperative treatment (controls). All samples for comparison are already present in our biobank.

Intervention

A daily dose of 40 mg Telmisartan (oral use) 2-4 weeks prior to aneurysm surgery.

Study burden and risks

Participating in this study only entails daily use of Telmisartan 2-4 weeks prior to surgery. The standard care is completely the same. Telmisartan is a registered drug used for treating hypertension. Although most people won't notice anything from using Telmisartan, side effects might occur. These are almost always mild side effects like dizziness and cold hands/feet. Side effects will resolve after stopping the study medication. To prevent any side effects from occurring patients are advised to take the medication at night.

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

Patients with an abdominal aortic aneurysm who are planned for elective open surgical repair.

Exclusion criteria

1. Renal insufficiency; eGFR < 50 ml/min
2. Bloodpressure < 120/70 mmHg
3. Abnormal liver function (liver enzymes > 3 times elevated of normal value)
4. Hypersensitivity for angiotensin II type 1 receptor antagonist or ACE inhibitor
5. Current usage of angiotensin II type 1 receptor antagonist or ACE inhibitor
6. Known significant renal stenosis (>70%) of one or both renal arteries
7. Active gout

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Micardis
Generic name:	Telmisartan
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	26-10-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-02-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2015-003674-32-NL
CCMO	NL55081.058.15