TElmisartan in the management of abDominal aortic aneurYsm (TEDY)

Published: 18-07-2012
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The aim of this study is to investigate if telmisartan reduces AAA growth

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

Summary

ID

NL-OMON43808

Source
ToetsingOnline

Brief title
TEDY

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

Intervention

Keyword: Abdominal aortic aneurysm, Medical Management, Telmisartan

Outcome measures

Primary outcome

The primary outcome measure will be the rate of growth of the AAAs estimated using the maximum orthogonal AAA diameter measured during the 2-year study period (ultrasound) and the change in total infrarenal volume.

Secondary outcome

I. Change in maximum infrarenal AAA diameter on repeat ultrasound at entry, 6, 12, 18 & 24 months;

II. Change in serum OPG, OPN, MMP-9 and TGFbeta-1 on repeated samples over 24 months;

III. Quality of life assessed by the SF36 (Quality of Life) questionnaire completed at entry, 12 & 24 months, which we have previously validated for use in elderly participants [62-64];

IV. There is increasing evidence that the efficacy of medications vary between individuals, with a growing interest in pharmacogenetics [75]. We have previously shown an association between genetic polymorphism in AT1 and AAA [43]. We will assess the presence of the AT1 1166C single nucleotide polymorphism (previously consistently associated with AAA) in recruited participants. This will enable us to analyse the impact of this polymorphism on response to telmisartan.

Study description

Background summary

Abdominal aortic aneurysm (AAA) is responsible for approximately 1000 deaths per year and is estimated to cost the health economy in excess of $80 million per year to manage in Australia. Early stage AAAs can be readily detected by screening or incidental imaging but currently this is of limited value as no effective medical therapy is available to inhibit AAA progression to a size where aortic rupture is a concern and surgery is therefore required. In a double blind, placebo controlled, randomised trial among participants with 35-49mm AAA, our aims are to investigate the efficacy of telmisartan as a possible treatment for AAA. We hypothesise that among patients with AAAs with an initial diameter of 35-49mm, 40mg of telmisartan administered daily for a 2 year period will reduce AAA expansion by 35% evidenced by:
1. Reduction in average yearly increase in AAA diameter from 2.0±1.7 to 1.5±1.3 mm
2. Reduction in average yearly increase in AAA volume from 6.20±5.90 to 4.65±4.42 cm3

Study objective

The aim of this study is to investigate if telmisartan reduces AAA growth

Study design

A randomized, placebo controlled study of Telmisartan (40 mg daily) or placebo in patients under surveillance for a small abdominal aortic aneurysm. The study will be performed in Australia, US and the Netherlands

Intervention

Telmisartan (40 mg, oid) or placebo

Study burden and risks

Telmisartan is a registered and well-tolerated drug with mild side-effects. Telmisartan treatment may induce hypo/orthostatic hypotension. For this reason all participants will be checked 2 weeks after the start of the study medication.

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

AAA measuring a maximum diameter of 35-49 mm on CTA or ultrasound
No current indication for AAA repair according to the treating physician or expectation that this will be revised within the next year
High likelihood of compliance with treatment over 24 months

Exclusion criteria

Contraindications to study treatment, including: renal impairment (i.e. creatinine >1.5x upper limit of normal [ULN]), known significant renal stenosis (>70%) of one or both renal arteries, chronic liver disease (i.e. cirrhosis or hepatitis) or abnormal liver function (i.e. ALT 1.5xULN), electrolyte imbalance and gout. No previous abdominal aortic surgery.

Current or planned usage of an AT1 blocker or ACE inhibitors

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	18-07-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	02-10-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-02-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-06-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-02-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	25-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-10-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	02-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2012-001859-39-NL
CCMO	NL40515.058.12