

Arterial stiffness, Blood Pressure and Cardiac output study; ABC-study;A Prospective, Multidisciplinary study of arterial stiffness measures in patients treated for aortic aneurysms in relation to blood pressure and cardiac output

Published: 04-05-2016

Last updated: 16-04-2024

Zie document PROTOCOL SYNOPSIS ABC study

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43043

Source

ToetsingOnline

Brief title

ABC study

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Aneurysms and artery dissections

Synonym

enlargement of the large blood vessel(aorta)/ aneurysm

Health condition

Hypertensie

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: eigen onderzoeksfonds

Intervention

Keyword: aneurysm, arterial stiffness, blood pressure, cardiac output

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Study burden and risks

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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

INCLUSION CRITERIA

1. Male or female at least 18 years old;
2. Informed consent form understood and signed and patient agrees to follow-up visits;
3. Have a infrarenal abdominal aortic aneurysm (AAA) with maximum sac diameter \geq 5.5cm, or an AAA \geq 4.5 cm which has increased by > 1.0 cm in the past year with a scheduled endovascular intervention

Exclusion criteria

EXCLUSION CRITERIA

1. Life expectancy < 2 years;

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2. Psychiatric or other condition that may interfere with the study;
3. Participating in another clinical study, interfering on outcomes;
4. Irregular pulse;
5. Presence of extensive peripheral arterial disease (ABI < 0.9 or obstruction validated on imaging)
6. Ruptured, leaking or mycotic aneurysm;

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-04-2017

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 04-05-2016

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register

CCMO

ID

NL57153.091.16