Intraoperative Wound Ventilation with Carbon Dioxide.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24534

Source
NTR

Brief title
N/A

Health condition

Aortic arch surgery.

Sponsors and support

Primary sponsor: St.-Antonius Ziekenhuis, Nieuwegein
departement of Cardio-thoracic Surgery
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Less microembolism assessed by Trans-Cranial Doppler (TCD) monitoring of the left and right middle cerebral artery.

Secondary outcome

Neurological outcome assessed by clinical neurological testing and neurocognitive outcome assessed by comprehensive neuropsychometric studies (intelligence, problem-solving, concentration, learning, memory, error-free performance, mood abnormalities, and dexterity are components of the general neuropsychological system, and all of these have been included in the term cognitive functions). These testings are performed the day before surgery, the day before hospital discharge and 3 months postoperatively.

Morphologic alterations of the brain are searched for by comparing preoperative and postoperative diffusion-weighted MR-imaging scans of the brain.

Study description

Background summary

The relationship between cerebral air microembolisms in open heart surgery and neurologic outcome remains unclear. It is also still questionable if the risk of air microembolism can be reduced by intraoperative wound ventilation by CO2 insufflation. Therefore, we will study the effect of CO2 insufflation into the sternal wound on the incidence of intraoperative cerebral microembolism and postoperative neurocognitive deficits (temporary neurological deficiency) and minor or major stroke. Morphological differences (between preoperative and postoperative imaging of the brain) will be searched for by diffusion-weighted MR-imaging.

Study objective

We hypothesize that the use of Carbon Dioxide (CO2) reduces the incidence of (air) microembolism during aortic arch surgery, and that it also positively influences the gross neurologic and/or the neurocognitive outcome of this kind of surgery.

Study design

N/A

Intervention

Patients will be randomized to receive peroperative carbondioxide wound ventilation or not. In one group peroperative carbon dioxide insufflation of the wound will be combined with conventional de-airing procedures at the end of the operation; in a second group only conventional de-airing procedures will be done.

Contacts

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Eligibility criteria

Inclusion criteria

Patients accepted for elective aortic arch surgery (with or without concomitant surgery on the ascending aorta or other heart related surgery).

Exclusion criteria

1. Emergency operation;

2. Severely calcified or sclerotic aorta or cerebropetal vessels;

3. Patients with history of central neurological events (minor or major strokes);

4. Patients with signs of infarcts on preoperative MR-imaging;

5. Patients with pre-existing atrial fibrillation;

6. Patients that are unable to cooperate or score poorly on preoperative neurocognitive testing;

7. Patients with history of alcohol disuse;

8. Patients with history of psychiatric disturbances.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2006
Enrollment:	60
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL518
NTR-old	NTR561
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A