The Impact of Intraoperative Carbon Dioxide Wound Ventilation on Cerebral Microembolic Load during Aortic Arch Surgery : a Prospective Randomized Clinical Trial using Transcranial Doppler Ultrasound

Published: 24-08-2006 Last updated: 14-05-2024

The primary objective of this study is to evaluate the impact of carbon dioxide field flooding on the quantitative intraoperative microembolic load of the brain during aortic arch surgery.A secondary objective is to evaluate any concomitant...

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON30090

Source ToetsingOnline

Brief title Carbon Dioxide Micro-Embolism Study

Condition

- Central nervous system vascular disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym

(minor, cognitive function, major or silent stroke), paralysis, postoperative stroke

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Research involving

Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carbon Dioxide (CO2), Micro-embolism, Transcranial Doppler

Outcome measures

Primary outcome

Number of cerebral microemboli counted on Transcranial Doppler ultrasound

recordings

Secondary outcome

Postoperative ischemic reactions in the brain assessed by diffusion-weighted

magnetic resonance imaging of the brain

Study description

Background summary

The presence of air emboli in open heart surgery implies an important risk for postoperative neurological damage. Flooding the operative field with carbon dioxide (CO2) has been used for displacing air from the thoracic cavity and cardiac chambers. The theoretical value of this technique is that carbon dioxide will displace air from the operative field because it is a heavier gas and because carbon dioxide emboli, if they occur, are better tolerated than air emboli.

Despite this impressive theoretical advantages, the use of carbon dioxide field flooding is not widespread. Probably, this is due a disbelieve in this technique because only small numbers of studies have tried to prove its effectiveness. Moreover, a prospective randomised study using Transcranial Doppler ultrasound (TCD) has never been done. With TCD the cerebral microembolic load can be measured directly. We hypothesize that the intraoperative cerebral embolic load can be reduced dramatically with the use of intraoperative carbon dioxide field flooding. But this has to be confirmed with intraoperative TCD.

Study objective

The primary objective of this study is to evaluate the impact of carbon dioxide field flooding on the quantitative intraoperative microembolic load of the brain during aortic arch surgery.

A secondary objective is to evaluate any concomitant difference in postoperative ischemic reactions in the brain assessed by diffusion-weighted MR-imaging (Magnetic Resonance Imaging).

Study design

Single-centre prospective randomzed double-blind clinical trial

Intervention

In one group carbon dioxide surgical field flooding is used intraoperatively and in the other group not

Study burden and risks

No clear risks according to the use of intraoperative wound ventilation with CO2 are known.

No blood samples are needed for this study.

No extra visits, physical examinations, questionnaires or diaries are necessary for this study.

One extra MRI brain scan will be done.

We anticipate no physical and physiological discomfort associated with participation.

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

all patients accepted for elective surgery on the ascending aorta and aortic arch via median sternotomy

Exclusion criteria

- emergency operation (including type A dissection)
- patients with a difficult transtemporal acoustic ultrasound *bone window*
- patients with claustrophobia and therefore unwilling to have magnetic resonance brain
- imaging or that have other contra-indications for this investigation (pacemakers, etc.)
- patients with a more than 60% stenosis or occlusion of one or both carotid arteries
- intraoperative technical failure of TCD registration

Study design

Design

Study phase: Study type: 3 Interventional

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Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	30
Туре:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	medical gas
Generic name:	Carbon Dioxide

Ethics review

Approved WMO	
Date:	24-08-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	12-10-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2006-003660-65-NL
ССМО	NL11765.100.06