Evaluation of EmBlocker*

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To study the efficacy of the EmBlocker* in heart operations. The EmBlocker* is placed in the thorax cavity and will reroute by the use of ultrasound the emboli in the aorta curve to the aorta descendens, in order to reduce the amount of emboli in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON30749

Source
ToetsingOnline

Brief title
NX-EM-02

Condition

- Coronary artery disorders
- Neurological disorders NEC

Synonym
cerebrovascular incident, stroke, TIA

Research involving
Human

Sponsors and support

Primary sponsor: Neurosonix Ltd
Source(s) of monetary or material Support: Bedrijf: Neurosonix Ltd;Rehovot;Israel

Intervention

Keyword: cardiac surgery, emboli, transcranial doppler

Outcome measures

Primary outcome

Primary efficacy endpoint: the amount of embolic signals, registered with the

TCD.

Primary safety endpoint: absence of device-related serious complications.

Secondary outcome

not applicable

Study description

Background summary

During heart surgery air emboli and solid emboli can enter the bloodstream as a result of surgical actions. Clamping of the aorta, cannulation, the removal of the aorta clamps and decannulation are all surgical actions which introduce emboli into the aorta. Via the bloodstream the emboli will reach either the aorta descendens or the carotids. Emboli in the cerebral arteries may cause (temporary) obstructions. This can result into permanent neurological damage, like neuro-psychological deficiency, or even a stroke. Air emboli are in comparison to solid emboli less damaging, as they do not cause a permanent obstruction, but in the brain even a temporary obstruction can cause damage.

Study objective

To study the efficacy of the EmBlocker* in heart operations. The EmBlocker* is placed in the thorax cavity and will reroute by the use of ultrasound the emboli in the aorta curve to the aorta descendens, in order to reduce the amount of emboli in the arteries of the brain. A reduction in the amount of emboli in the arteries of the brain can result in a decrease of post-operative neurological damage.

Study design

The study will be carried out single blinded in a population of 10 control patients and 20 study patients. In the control group the patients will undergo a standard heart operation (CABG or bypass operation), with Transcranial Doppler monitoring and blood tests, but no EmBlocker* will be placed. The

results will be compared to the patients of the study group, undergoing a standard heart operation (CABG or bypass operation) with transcranial Doppler monitoring, blood tests and the use of the EmBlocker*.

Intervention

The EM-blocker* shall be activated at different times during the operation. These moments are mostly at times the aorta is manipulated, like during cannulation and decannulation, the insertion of the cardioplegic needle and aortic clamping.

Study burden and risks

The risks involved for the patients in the study group are the possibility of thermal damage and an increase in the amount of emboli in the aorta descendens. The risk for thermal damage is minimized by lowering the temperature of the transducer by means of the continuous cooling of the transducer and by keeping the exposure to this energy at the lowest possible level. Previous studies did not reveal any thermal damage to patients. The major part of the created emboli shall reach the aorta descendens without the intervention of the EmBlocker*. Therefore the intervention of the EmBlocker* will only cause a relatively small increase in the amount of emboli in the aorta descendens. Furthermore, mostly air emboli will be rerouted and these are less dangerous in other organs than the brain.

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

65Undergoing an elective CABG surgery
Left ventricular ejection fraction above 30%
Patient has the ability to understand the nature of the study and provide written informed consent

Exclusion criteria

Off-pump surgery
Temporal window not detected for transcranial doppler measurements
Re-do procedure
Emergency operation required
Has a life threatening debilitating disease other than cardiac
Stroke history (pre-excisting TIA and/or CVA)
Patients with renal failure requiring dialysis
The patient has been treated with an investigational drug or device within 30 days prior to surgery and/or will be treated peri- or post-operatively

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	EmBlocker
Registration:	No

Ethics review

Approved WMO Date:	25-07-2007
Application type:	First submission
Approved WMO Date:	21-11-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL16318.068.07