Exploratory study regarding the use of Neurophysiological Monitoring Techniques to Detect Spinal Cord Ischemia in Patients after Thoracoabdominal Aortic Aneurysm Repair

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Ethical review	Approved WMO
Status	Completed
Health condition type	Spinal cord and nerve root disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52997

Source
ToetsingOnline

Brief title
Evaluating monitoring techniques for postoperative spinal cord ischemia

Condition

- Spinal cord and nerve root disorders
- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
myelum ischemia, spinal cord damage

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,industrie/bedrijf,Medtronic

Intervention

Keyword: Aorta aneurysm repair, Neuromonitoring, Prevention, Spinal ischemia

Outcome measures

Primary outcome

The study will consist of two parts. Part one refers to the *intraoperative phase*, the period when patients are fully sedated. This contains the whole period during surgery. Part two refers to the *postoperative phase*, the period after surgery when patients are fully sedated and when the level of sedation has been decreased and patients are only partially sedated and eventually awake.

1. During part one, the *intraoperative phase*, feasibility of the techniques described above will be determined and characteristics will be described. An association with the current gold standard (MEP signals) will be determined.

2. During part two, the *postoperative phase*, feasibility of the techniques described above will be determined and characteristics will be described. An association with hemodynamic characteristics as well as paraparesis at the end of the postoperative period (after the patient wakes up) will be determined.

Secondary outcome

As described in section above.

Study description

Background summary

During open surgery of a thoraco-abdominal aortic aneurysma (TAAA), diminished blood flow to the myelum can result in hypoxia, compromising proper function of the spinal cord. Intraoperatively, motor evoked potentials (MEP) are elicited to measure the functional integrity of the spinal cord. MEPs have proven to be a reliable marker of spinal cord ischemia. Moreover, these potentials react within minutes, which facilitates interventions to restore the blood flow. Monitoring intraoperatively with this ancillary test has reduced the rate of paraparesis to < 5%.
Unfortunately, in the early postoperative period, spinal cord vulnerability is high. Therefore, some patients develop paraparesis, not during the surgical procedure, but after the surgical procedure. Postoperatively, suboptimal blood flow may lead to critical loss of function. This inadequate perfusion results in *delayed paraparesis*. In the postoperative patient, it is not possible to measure MEPs when sedation is decreased, due to the high intensity of the electrical stimulus, which is unacceptably painful in the unanesthesized or partially anesthesized patient.
Therefore ancillary tests are needed which can detect spinal cord ischemia postoperatively early, thus preceding the phase with clinically overt paraparesis. The test should be reliable and easy to perform for an extended period of time (up to several days).

Study objective

The purpose of this study is to explore the usefulness of various neurophysiological tests regarding accuracy and feasibility for the detection of spinal cord ischemia. In particular, to find a diagnostic test which is acceptable for the unanesthesized or partially anesthesized patient and therefore can also be performed postoperatively.

The following candidate tests will be examined:
1. Oxygenation measurements of the paraspinal muscles using Near-infrared spectroscopy (NIRS).

Study design

Feasibility study.

Study burden and risks

There is no risk associated with participation in the study and the study is non-therapeutic. Intraoperatively, the patient is fully sedated and the burden is comparable to the standard care (intraoperative neuromonitoring). Postoperatively, during the period that the patient is fully sedated, additional burden of the measurements will be minimal.
There may be discomfort due to permanent attachment of optodes to the skin overlying the paraspinal muscles. If any skin changes are noticed, this will be documented and if necessary the measurements will be discontinued.
Clinical and neurological examination is performed as in standard patient care.

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

Age >= 18 years
Thoraco-abdominal aneurysm (TAA) of the descending aorta: Crawford type I,II, III, IV or V
Repair using open surgical or endovascular procedure.
Undergoing monitoring by motor evoked potentials (MEP) as part of the standard surgical procedure.

Exclusion criteria

Age < 18 years.
Aneurysm only in ascending part of the aorta
Standard contraindications for motor evoked potential (MEP) monitoring.
Standard contraindications for electrode placement (skin wounds, etc.)
No informed consent can be obtained prior to the procedure

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-01-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-09-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2022
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	NL58137.068.16

Study results

Date completed: 01-02-2024

Summary results
Trial ended prematurely