Assessment of intraoperative embolism during spinal surgery with transesophageal echocardiography.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON34704

Source
ToetsingOnline

Brief title
Embolism during spinal surgery.

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
embolism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: embolism, spinal surgery, trans esophageal echocardiography

Outcome measures

Primary outcome

Incidence and severity of embolic processes during spinal surgery, measured

using transoesophageale echocardiography.

Secondary outcome

- Cardiopulmonary function (SO2, PO2, pCO2, etc.)

- Blood pressure (systolic, diastolic and mean arterial blood pressure)

Study description

Background summary

Sudden perioperative cardiopulmonary dysfunction caused by emboli is a known complication of bone and joint surgery. Fat-and bone marrow emboli occur frequently during drilling into intramedullary canals of long bones, as happens during fixation of fractures or joint replacement surgery. These emboli are for orthopedic surgeons and anesthesiologists a real concern because they can lead to serious perioperative complications and are potentially fatal.

It is unknown whether embolism during spinal surgery resulting from the insertion of instrumentation (pediclesrews) have a similar deleterious effect on cardiopulmonary function. The incidence of (sub)clinical embolic processes during surgery on the spine remains a topic of discussion.

Study objective

Our primary study objective is whether visualizing and scoring of emboli is technically feasible. Secondary we want to asses the occurence and incidence of embolic events during spinal instrumentation surgery by intraoperative monitoring with TEE. In addition we want to evaluate the effect of intraoperative embolism on cardiopulmonary function.

Study design

Observational feasibility study conducted in the University Medical Center Utrecht.

Study burden and risks

The use of TEE is considered as non-invasive, especially in patients under anesthesia. Complications are rare, a 0-0,5% complication rate is reported in a study of 7200 patients who underwent TEE. Most of these complications are related to insertion of the ultrasound probe in the esophagus. Extreme caution when inserting the probe will even minimize potential complications.

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

Adult patients undergoing elective spinal surgery where the use of pedicle screws and/or vertebroplasty is planned.

Exclusion criteria

A contra-indication for the use of transoesophageal echocardiography: oropharyngeal carcinoma, esophageal varices, esophageal stricture, esophageal diverticulum, esophagitis, Mallory-Weiss tear, recent upper gastro-intestinal hemorrhage, gastric ulcer, symptomatic hiatal hernia.
Indication for acute surgery: traumatic injury, metastatic fracture

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):	01-04-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-06-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL30307.041.10