Paradoxical and venous Gas Embolism During Hysteroscopic Surgery Detected by Trans Esophageal Echocardiography: A comparison using either bipolar or monopolar diathermia

Published: 02-12-2008
Last updated: 20-06-2024

To determine the incidence and grade of venous emboli and/or paradoxical gas emboli during hysteroscopy surgery using TOE. In addition, a comparison will be made using either bipolar or monopolar diathermia. Knowing the incidence and severity of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON31886

Source
ToetsingOnline

Brief title
Venous and pardoxical Embolism During Hysteroscopic Surgery

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
gas embolism. Air in blood during gynaecological surgery, hysteroscopic surgery

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: OLVG wetenschapsfonds

Intervention

Keyword: gas-embolism, hysteroscopic surgery

Outcome measures

Primary outcome

The primary study parameter is the appearance of any embolic event either

venous or paradoxical of origin. A four point grading scale is used to define

the severity of the event. The duration of the embolic phenomena will be

recorded.

Secondary outcome

nog invullen!

Study description

Background summary

We have observed severe venous air and paradoxical gas embolism using trans-oesophageal echocardiography (TOE) in a patient without a patent foramen ovale undergoing bipolar trans cervical resection of the endometrium. Although venous emboli during monopolar hysteroscopic surgery is a common finding, its association with paradoxical embolism has not been reported before. Whether bipolar diathermia, in contrast to monopolar diathermia, induces more venous and paradoxical gas embolism is unknown and therefore subject of our study.

Study objective

To determine the incidence and grade of venous emboli and/or paradoxical gas emboli during hysteroscopy surgery using TOE. In addition, a comparison will be made using either bipolar or monopolar diathermia. Knowing the incidence and severity of embolic events may help in understanding the pathophysiology and

thereby help in preventing these potentially lethal events.

Study design

After receiving informed consent patients will be included in a randomised study using either monopolar or bipolar diathermia. The ultra sound probe will be positioned into the oesophagus to obtain a four chamber view. Rating of intra-operative embolic events will be performed by a blinded observer using established criteria.

Intervention

monopolar versus bipolar diathermia

Study burden and risks

Adverse and serious adverse events related to the hysteroscopic procedure will be treated according to generally accepted guidelines.
First off all the hysteroscopic procedure is stopped thereafter the primary goal is the protection and maintenance of vital functions. Measures may include cardiopulmonary resuscitation.

The reported overall morbidity (0.2%) and mortality (0%) rates of intraoperative transesophageal echocardiography (TEE) were determined in a retrospective case series of 7200 adult, anesthetized cardiac surgical patients. The most common source of TEE-associated morbidity was odynophagia (0.1%), which resolved with conservative management. These results suggest that TEE is a safe diagnostic tool for the management of surgical patients.
If any adverse and serious events (SAE) related to the installation of the TOE probe occur (oesophageal lacerations, bleeding etcetera) they will be treated following consultation of a gastroenterologist and surgeon.

All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.
A serious adverse event is any untoward medical occurrence or effect that at any dose results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients* hospitalisation;
- results in persistent or significant disability or incapacity;
- is a new event of the trial likely to affect the safety of the subjects, such as an unexpected outcome of an adverse reaction, lack of efficacy of an IMP used for the treatment of a life threatening disease, major safety finding from a newly completed animal study, etc.

All SAEs will be reported to the accredited METC that approved the protocol,

according to the requirements of that METC.

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

The study population consists of patients who are scheduled to undergo a TCR-M or a TCR-E on an elective basis. Patients must be classified as ASA 1 or 2. Minimum expected operation time must be at least * hour.
The control group will consist of ASA 1-2 patients undergoing non-surgical hysteroscopy, as is carried out in conjunction with diagnostic laparoscopy, performed during infertility evaluation.

Exclusion criteria

Exclusion criteria include age younger than 18 or higher than 70 and a history of pulmonary embolism, cardiac disease or esophageal disease such as stenosis, obstruction, ulcerative esophagitis or gastric haemorrhage. Patients with communication difficulties will be excluded. Procedures that are expected to be short lasting less than * hour are excluded.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2008
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
Other	1357
CCMO	NL23739.100.08