

# Gas Embolism during Hysteroscopic Surgery Detected by Esophageal Echocardiography: A comparison using two different electrocautery cutting techniques.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23264

### Source

NTR

### Brief title

PAVEG

### Health condition

To determine the incidence and grade of venous emboli and/or paradoxical gas emboli during hysteroscopy surgery. 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.

keywords: hysteroscopy, paradoxical emboli, venous emboli, trans oesophageal echocardiography.

In Dutch: hysteroscopie, veneuze gasembolie. paradoxale embolie, slokdarm echocardiografie

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

Percentage venous or paradoxical emboli

### Secondary outcome

Duration of emboli observation

## Study description

### Background summary

Rationale:

Venous emboli during monopolar hysteroscopic surgery is a common finding, its association with paradoxical embolism was reported recently. Whether bipolar diathermia, in contrast to monopolar diathermia, induces more venous and paradoxical gas embolism is unknown and therefore subject of our study.

Objective:

To determine the incidence and grade of venous emboli and/or paradoxical gas emboli during hysteroscopy surgery using trans oesophageal echocardiography. 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.

## Study population:

Forty-two patients (ASA classification 1 or 2) scheduled for Trans Cervical Myoma resection (TCR-M) or Trans Cervical endometrium resection (TCR-E) will be included. Exclusion criteria include age younger than 18 or higher than 70 and a history of pulmonary embolism, cardiac disease or oesophageal disease.

## Intervention:

Under general anaesthesia a TOE probe will be inserted in all patients to observe and record embolic events.

## Main study parameters/endpoints:

The main 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.

## Study objective

We have observed severe venous air and paradoxical gas embolism using trans-oesophageal echocardiography (TOE) in a patient 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 design

0. Under general anesthesia before start of diathermia
1. During diathermia after 10 minutes
2. Every 10 minutes thereafter
3. After stopping procedure under general anesthesia

## Intervention

Patients will be subjected to hysteroscopy using either mono or bipolar diathermia. Under general anaesthesia a transoesophageal echocardiography probe will be inserted in all patients to observe and record embolic events.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Healthy patients (ASA classification 1 or 2) scheduled for Trans Cervical Myoma resection (TCR-M) or Trans Cervical endometrium resection (TCR-E) will be included.

### Exclusion criteria

Exclusion criteria include age younger than 18 or higher than 70 and a history of pulmonary embolism, cardiac disease or oesophageal disease.

## Study design

### Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-10-2008  
Enrollment: 42  
Type: Anticipated

## Ethics review

Not applicable  
Application type: Not applicable

## 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
NTR-new	NL1308
NTR-old	NTR1357
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A