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

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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…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23264

Bron
Nationaal Trial Register

Verkorte titel
PAVEG

Aandoening

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

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage venous or paradoxical emboli

Toelichting onderzoek

Achtergrond van het onderzoek

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 an 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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 an record embolic events.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1308
NTR-old	NTR1357
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A