

The effect of administration of terlipressine in the cervix of the uterus on the amount of uptake of fluid, formation of gas bubbles and the circulation during hysteroscopy

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Intracervical installation of terlipressin reduces the incidence and severity of gas embolism and the amount of intravasation during hysteroscopic surgery

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28576

Source

Nationaal Trial Register

Brief title

HYSTER

Health condition

myoma. menorrhagia

Sponsors and support

Primary sponsor: L.E. Overdijk

OLVG, Oosterpark 9, 1091 AC Amsterdam, l.e.overdijk@olvg.nl, 020-599111

Source(s) of monetary or material Support: self financing research

Intervention

Outcome measures

Primary outcome

to determine whether the intracervical insallation of terlipressin reduces the inncidence and severity of gas embolsim as detected by trans oesophageal echocardiography (TOE)

Secondary outcome

to study the effect of intracervical terlipressin on the amont of intravasation, global hemodynamics, myocardial ventricular systolic strain and myocardial diastolic funcion using TOE. A substudy will be done analysing the laboratoy results to determine elceltrlyte changes and assessing acid-base disturbances.

Study description

Background summary

TCR-M an TCR-E are safe hysteroscopic minimal invasive procedures. However, in a previous study we observed by TOE venous gas embolsim in almost every patient. This might be a potentially dangerous phenomenon. Hysteroscopic derived gas embolism has been shown to be correlated to the amount of intravasation. The installation of intracervical vasopressin has been shown to limit the amount of intravasation, therefore its use may be beneficial in hysteroscopic surgery leading to a lower incidence and severity of gas embolism. We use terlipressin (a synthetic long acting analogue of vasopressin)instead of vasopressin because vaspressin is not avalibale in our country, assuming terlipressine has the same effect on intravasation.

Study objective

Intracervical installation of terlipressin reduces the incidence and severity of gas embolsim and the amount of intravasation during hysteroscopic surgery

Study design

during surgery till 3 hours postoperative

Intervention

Intracervical installation of terlipressin vs placebo

Contacts

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Eligibility criteria

Inclusion criteria

48 patients (ASA classification 1 or 2) scheduled for trans cervical resection of large type 1-2 myomas (TCR-M) or extensive trans cervical endometrium resection (TCR-E)

Exclusion criteria

Trans cervical operations of small myomas and minor TCR-E procedures.

Short lasting procedures of < 1/2 hour.

Contraindication for transesophageal echocardiography (severe esophageal or gastric disease, hepatic cirrhosis or known esophageal varices).

Patients < 18 yr or > 70 yr.

History of pulmonary embolism, cardiac disease or esophageal disease. Patient with language barrier.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2013
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41343
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5344
NTR-old	NTR5577
EudraCT	EUCTR2013-000006-28-NL
CCMO	NL45004.100.13
OMON	NL-OMON41343

Study results