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 embolsim and the amount of intravasation during hysteroscopic surgery

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28576

Bron
Nationaal Trial Register

Verkorte titel
HYSTER

Aandoening

myoma. menorrhagia

Ondersteuning

Primaire sponsor: L.E. Overdijk
OLVG, Oosterpark 9, 1091 AC Amsterdam, l.e.overdijk@olvg.nl, 020-599111
Overige ondersteuning: self financing research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

during surgery till 3 hours postoperative

Onderzoeksproduct en/of interventie

Intracervical installation of terlipressin vs placebo

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

48 patiens (ASA classification 1 or 2) secheduled for trans cervical resection of large type 1-2 moma's (TCR-M) or extensive trans cervical endometrium resection (TCR-E)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Trans cervical operations of small myoma's and minor TCR-E procedures.

Short lasting procedures of < 1/2 hour.

Contraindication for transesophageal echocardiography (severe oesopageal or gastric disease, hepatic cirrhosis of known oesphageal varices.

Patients < 18 yr or > 70 yr.

Histroy of pulmonary embolism, cardiac disease or oesphageal disease. Patient wih language barrier.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41343
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten