

HSG versus HyFoSy: Is er een verschil in pijnscore tussen deze twee tubatesten?

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The primary hypothesis is that tubal patency test by a HyFoSy procedure is less painful compared to tubal patency test by a hysterosalpingography.

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

Samenvatting

ID

NL-OMON21432

Bron

Nationaal Trial Register

Verkorte titel

VAS Study

Aandoening

Subfertility, Tubal patency testing, painscores

Ondersteuning

Primaire sponsor: VU University Medical Centre

Overige ondersteuning: Material support: GynaecologiQ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VAS pain scores.

Toelichting onderzoek

Achtergrond van het onderzoek

When a couple search for help because of the inability to conceive after one year of trying, they will attend a fertility clinic and get a fertility work-up at the gynaecologist. Tubal patency testing is part of this fertility work-up. There are several tests available for tubal patency testing, including laparoscopy with chromopertubation of the fallopian tubes, hysterosalpingography (HSG), Hysterosalpingo Contrast Sonography (HyCoSy) and Hysterosalpingo-foam Sonography (HyFoSy).

A commonly used medium for HyCoSy was Echovist, but this medium has become no longer available for patency testing because of a possible allergic reaction on this medium when known with galactose allergy. So that meant that there was no sonographic tubal patency test available anymore.

In 2007 a new medium (Ex-Em-gel®) for gynaecologic sonography was introduced by GynaecologiQ. This is a non(embryo-) toxic gel, containing hydroxyethylcellulose and glycerol. This medium can be used for sonographic patency testing; Hysterosalpingo-foam Sonography (HyFoSy). During the sonography, a little amount of foam is introduced into the uterine cavity through a little cervical balloon-less applicator, connected to a syringe with foam. The foam is created by rigorously mixing 10 ml ExEm-gel® with 10 ml of purified water in a 20 ml syringe. This recipe turned out to be excellent for creating foam that was sufficiently stable to show echogenicity for at least 5 minutes and for providing sufficient fluid to pass through patent tubes.

Recently Emanuel et al showed in their prospective observational cohort study that HyFoSy is a successful procedure to demonstrate tubal patency as a first step office procedure. In 78 % there was no need for HSG after HyFoSy.

The aim of our study is to investigate if a HyFoSy is less painful compared to the first step office procedure for tubal patency testing: HSG. The fact that 78% of subfertile women, with a low risk of tubal pathology, don't need HSG. Gives us a need to know if a HyFoSy is less aggravating compared to HSG.

Doel van het onderzoek

The primary hypothesis is that tubal patency test by a HyFoSy procedure is less painful compared to tubal patency test by a hysterosalpingography.

Onderzoeksopzet

20 minutes post HyFoSy or HSG.

Onderzoeksproduct en/of interventie

Tubal patency testing by Hysterosalpingo-Foam Sonography versus Hysterosalpingography.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women between 18-41 years;
2. Low risk for tubal pathology according to medical history;
3. Chlamydia Antibody Titre (CAT) negative;
4. Valid indication for patency testing in the fertility work-up or before intra-uterine insemination treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known or high risk for tubal pathology, CAT positive;
2. Known contrast (iodine) allergy;
3. If not willing or able to sign the informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2012
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37574

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3310
NTR-old	NTR3457
CCMO	NL40536.029.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37574

Resultaten

Samenvatting resultaten

N/A