

Water-versus oliehoudend contrast voor het baarmoederonderzoek.

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The primary hypothesis is that flushing of the fallopian tubes is more effective with an oil based contrast medium compared to a water based contrast medium in terms of ongoing pregnancy.

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

Samenvatting

ID

NL-OMON23300

Bron

Nationaal Trial Register

Verkorte titel

H2Olie studie

Aandoening

Subfertility, tubal patency testing

Ondersteuning

Primaire sponsor: VU University Medical Centre

Overige ondersteuning: zelfgefinancierd

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy defined as registered heartbeat on ultrasound beyond 12 weeks of gestation within the first 6 months after randomisation.

Toelichting onderzoek

Achtergrond van het onderzoek

In the evaluation of female subfertility, hysterosalpingography (HSG) is an important examination because of its diagnostic value. The procedure delineates the uterine cavity contours and the rugation and the patency of the fallopian tubes. Since the introduction of HSG as a diagnostic test, various contrast media have been used, from water-soluble to oil-soluble, ionic to nonionic, and high osmolarity to low osmolarity.

A possible therapeutic effect of diagnostic tubal patency testing has been debated in the literature for more than 50 years.

There are some small studies that show that flushing with Oil-soluble contrast medium (OSCM) has a significant higher odds ratio of live birth compared to flushing with Water-soluble contrast medium (WSCM). But other small studies showed no significant different in odds ratio of pregnancy or live births after flushing during HSG examination with OSCM or WSCM.

The purpose of this multi centre, randomised controlled trial, is to determine whether at HSG the use of oil-based contrast media results in higher ongoing pregnancy and live birth rates compared to the use of water-based contrast media.

Doel van het onderzoek

The primary hypothesis is that flushing of the fallopian tubes is more effective with an oil based contrast medium compared to a water based contrast medium in terms of ongoing pregnancy.

Onderzoeksopzet

6 months post hysterosalpingography.

Onderzoeksproduct en/of interventie

Tubal flushing with oil based contrast medium versus water based contrast medium.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18 up to and including 39 years;
2. Subfertility of at least one year;
3. Chlamydia antibody titer (CAT) negative;
4. Low risk of tubal pathology according to the medical history;
5. Valid indication for HSG in the fertility work-up or before intra uterine insemination treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Endocrino-pathological diseases as: PCOS, Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type 1;
2. Known or high risk for tubal pathology, CAT positive;
3. Known contrast (iodine) allergy;
4. Male subfertility defined as a post-wash total motile sperm count $< 3 \times 10^6$ spermatozoa/ml;
5. If not willing or able to sign the consent form.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	1080
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 01-02-2012

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32658

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3120
NTR-old	NTR3270
CCMO	NL26044.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32658

Resultaten

Samenvatting resultaten

N/A