

Waterhoudend contrast versus oliehoudend contrast voor het doorspuiten van de eileiders tijdens een baarmoederfoto - de lange termijn effecten.

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The primary hypothesis is that the effect of tubal flushing with oil-based contrast results in higher ongoing pregnancy rates compared to water-based contrast medium.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24080

Bron

Nationaal Trial Register

Verkorte titel

H2Oil long-term follow-up

Aandoening

Subfertility

H2Oil

Hysterosalpingography

HSG

Oil-based contrast medium

Water-based contrast medium

Tubal patency testing

Ondersteuning

Primaire sponsor: VU University Medical Centre Amsterdam

Overige ondersteuning: VU University Medical Centre Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy rate following HSG.

Toelichting onderzoek

Achtergrond van het onderzoek

Recently, we published the H2Oil study: Oil-Based or Water-Based Contrast for Hysterosalpingography in Infertile women. The ongoing pregnancy rates within six months after randomization were 39.7% in the oil-group compared to 29.1% in the water-group. At six months, this difference between tubal flushing with lipiodol and water based contrast was still increasing. Firstly, it is unclear if this difference will increase beyond 6 months. Secondly, it is unclear if couples after having had a first child, still benefit from the single procedure of tubal flushing when they aim to get a second child. Thirdly, the economic impact of the use of oil-based contrast is unclear. It is likely that the 6 month difference in pregnancy rate will result in a decrease of the use of additional treatments, of which IVF is the most important one.

Based on these three questions, we propose a long-term follow-up of couples that participated in the H2Oil study.

Doel van het onderzoek

The primary hypothesis is that the effect of tubal flushing with oil-based contrast results in higher ongoing pregnancy rates compared to water-based contrast medium.

Onderzoeksopzet

Follow-up until 3 to 5 years after randomization.

Onderzoeksproduct en/of interventie

After given informed consent, women will be asked to fill in the questionnaire and return it.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participants of the Water- versus Oil (H2Oil) study who were recruited in 27 hospitals (4 academic, 12 teaching and 11 non-teaching hospitals) in the Netherlands, between February 2012 and October 2014.

Inclusion criteria of the H2Oil study:

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)

Exclusion criteria of the H2Oil study:

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:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart

(Verwachte) startdatum: 01-07-2017
Aantal proefpersonen: 1119
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 19-07-2017
Soort: Eerste indiening

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	NL6402
NTR-old	NTR6577
Ander register	2017.221 : VU University Medical Centre

Resultaten

Samenvatting resultaten

Dreyer K, van Rijswijk J, Mijatovic V, et al. Oil-Based or Water-Based Contrast for Hysterosalpingography in Infertile Women. N Engl J Med. 2017; May 25: 376:2043-2052.
Kieslinger DC, .. van Rijswijk J et al. Embryo selection using time-lapse analysis (Early Embryo Viability Assessment) in conjunction with standard morphology: a prospective two-center pilot study. Hum Reprod. 2016;31(11):2450-2457.
Becker JH, van Rijswijk J et al. Is intrapartum fever associated with ST-waveform changes of

the fetal electrocardiogram? A retrospective cohort study. BJOG. 2012;119(11):1410-6.