H2Oil2: Oil- based versus water-based contrast media for hysterosalpingography (HSG) in infertile women with unevaluated indications: a randomized controlled trial

Gepubliceerd: 01-08-2019 Laatst bijgewerkt: 19-03-2025

We hypothesize that tubal flushing at hysterosalpingography (HSG) with oil-based contrast will result in higher pregnancy and live birth rates as compared to tubal flushing at HSG with water-based contrast in the target population.

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

Samenvatting

ID

NL-OMON24142

Bron
Nationaal Trial Register

Verkorte titel
H2Olie2

Aandoening

Subfertility, tubal patency testing

Ondersteuning

Primaire sponsor: Amsterdam UMC, VUmc
Overige ondersteuning: ZonMw, Guerbet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Conception leading to live birth with a positive pregnancy test within 6 months after randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: We hypothesize that tubal flushing at hysterosalpingography (HSG) with oil-based contrast will result in higher pregnancy and live birth rates as compared to tubal flushing at HSG with water-based contrast in women: with an ovulation disorder, at high risk for tubal pathology and/or ≥38 years of age, which will lead to a reduction in the need for expensive fertility treatments like IVF and/or ICSI, and will therefore be a cost effective strategy.

Objective: The objective of the proposed study is to assess the effectiveness and costeffectiveness of the use of oil versus water-based contrast medium in terms of live birth in women undergoing HSG, who:
1: have ovulation disorders and/or;
2: are at high risk for tubal pathology and/or;
3: are 39 years of age or over.

Study design: Multicenter, randomized controlled trial with a cost-effectiveness analysis alongside it.

Study population:
We will study women:
1: with ovulation disorders and/or;
2: at high risk for tubal pathology and/or;
3: are 39 years of age or over.

Intervention: We will compare tubal flushing at HSG with oil-based contrast (intervention) versus tubal flushing with water-based contrast (control).

Main study parameters/endpoints: The primary outcome is conception leading to live birth, with a positive pregnancy test preceding the pregnancy within 6 months after randomization. We will also study time-to-pregnancy. Our hypothesis is that HSG with oil-based contrast will increase pregnancy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As we compare strategies (HSG with oil-based contrast versus HSG with water-based contrast) that are already applied in current practice, no additional risks or burdens are expected from the study.

Doel van het onderzoek

We hypothesize that tubal flushing at hysterosalpingography (HSG) with oil-based contrast will result in higher pregnancy and live birth rates as compared to tubal flushing at HSG with water-based contrast in the target population.

Onderzoeksopzet

Follow-up 6 months after randomization

Onderzoeksproduct en/of interventie

HSG as tubal patency test with oil-based contrast versus HSG as tubal patency test with water-based contrast.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, women must meet one of the following criteria:
1: with ovulation disorders (ovulation disorders will be defined as less than 8 menstrual cycles per year) or;

2: at high risk for tubal pathology (high risk for tubal pathology will be defined as a positive chlamydia infection, a pelvic inflammatory disease, known endometriosis, abdominal surgery (including tubectomy for ectopic pregnancy and appendectomy) and/or peritonitis in the medical history) or;
3: 39 years of age or over

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Iodinated contrast agent allergy
- Male subfertility defined as total motile sperm count < 3 x10^6 spermatozoa/ml
- Not willing or able to sign the consent form

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-08-2019
Aantal proefpersonen:	930
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N / A

Ethische beoordeling

Positief advies

Datum:	01-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52387
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7925
CCMO	NL66079.029.19
OMON	NL-OMON52387

Resultaten

Samenvatting resultaten
N / A