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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24142

Source
Nationaal Trial Register

Brief title
H2Olie2

Health condition

Subfertility, tubal patency testing

Sponsors and support

Primary sponsor: Amsterdam UMC, VUmc
Source(s) of monetary or material Support: ZonMw, Guerbet

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Biochemical pregnancy, clinical pregnancy, ongoin pregnancy
- Miscarriage, ectopic pregnancy, multiple pregnancy
- Time to pregnancy
- Complications following HSG (infection, intravastion)
- Pregnancy outcomes (f.e. birth weight)
- Pregnancy complications
- Stillbirth
- Thyroid function of the woman (before and 1 month after HSG)
- Neonatal outcomes
- Additional fertility treatments (Intra-uterine insemination, IVF, IVF/ICSI)
- Costs within 6 months after randomization
- Thyroid function of neonate (determined by heelprick)

Study description

Background summary

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.

Study objective

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.

Study design

Follow-up 6 months after randomization

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2019
Enrollment:	930
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N / A

Ethics review

Positive opinion
Date: 01-08-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52387
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N / A