H2Oil-timing: Tubal flushing with oil-based contrast during HSG in subfertile women: Is early flushing effective and costeffective as compared to delayed flushing?

No registrations found.

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

Summary

ID

NL-OMON23111

Source
NTR

Brief title
H2Olie-timing

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

The primary outcome is time to live birth, calculated from positive pregnancy test and within 12 months after randomization.

Secondary outcome

- Live birth
- Clinical pregnancy, ongoing pregnancy
- Miscarriage, ectopic pregnancy, multiple pregnancy
- Complications following HSG (infection, intravasation)
- 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 12 months after randomization
- Thyroid function of neonate (determined by heelprick)

Study description

Background summary

Rationale: We hypothesize that direct tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up results in 10% more ongoing pregnancies and a shorter time to pregnancy compared to delayed tubal flushing 6 months after fertility work-up is completed in women at low risk for tubal pathology, which will lead to a reduction in the need for expensive fertility treatments like IVF and/or ICSI, and will therefore be an effective andcost effective strategy.

Objective: The aim of this study is to determine whether direct tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up results in 10% more ongoing pregnancies and a shorter time to pregnancy, which will therefore be effective and cost-effective compared to delayed tubal flushing 6 months after fertility work-up is completed in women at low risk for tubal pathology.

Study design: We plan a multicentre randomized controlled trial with an economic analysis alongside it. Infertile women at low risk for tubal pathology will be randomized to direct tubal flushing with oil-based contrast incorporated in the fertility work-up or delayed tubal flushing 6 months after fertility work-up is completed.

Study population: Infertile women under 39 years of age, who have a spontaneous menstrual cycle and at low risk for tubal pathology, undergoing fertility work-up.

Intervention: Direct tubal flushing with oil-based contrast at HSG as part of the fertility work-

up compared to delayed tubal flushing 6 months after the fertility work-up is completed.

Main study parameters/endpoints: The primary outcome is time to live birth, calculated from positive pregnancy test and within 12 months after randomization. Our hypothesis is that tubal flushing at HSG with oil-based contrast incorporated in the fertility work-up will result in 10% more ongoing pregnancies and a shorter time to pregnancy, and thus reducing the need for ART and reducing costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As we compare strategies (tubal flushing with oil-based contrast at HSG incorporated in the fertility work-up versus 6 months after completion of fertility work-up) that are already applied in current practice, no additional risks or burdens are expected from the study.

Study objective

Our hypothesis is that tubal flushing at HSG with oil-based contrast incorporated in the fertility work-up will result in 10% more ongoing pregnancies and a shorter time to pregnancy, and thus reducing the need for ART and reducing costs.

Study design

Follow-up 12 months

Intervention

Direct HSG with oil-soluble contrast, incorporated in the fertility workup (intervention).
Delayed HSG with oil-soluble contrast 6 months after fertility workup (control).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, women must meet all of the following criteria:
- Between 18-39 years of age
- Spontaneous menstrual cycle
- Perceived low risk for tubal pathology
- Undergoing fertility work-up

Exclusion criteria

- Women with known endocrine disorders (e.g. the polycystic ovary syndrome, diabetes, hyperthyroidism and hyperprolactinemia)
- Ovulation disorders defined as less than eight menstrual cycles per year
- Iodine allergy
- Male subfertility defined as a post-wash 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):	22-08-2019
Enrollment:	554

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: 52895
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7926
CCMO	NL62838.029.19
OMON	NL-OMON52895

Study results

Summary results
N/A