Is, in infertile women undergoing a basic fertility work-up, tubal flushing with oil-based contrast medium during hysterosalpingography (HSG) cost-effective compared to tubal flushing by hysterosalpingo-foam sonography (HyFoSy)? A randomized controlled trial.

Published: 17-03-2023
Last updated: 21-12-2024

The main objective of this study is to determine whether tubal flushing with oil-based contrast during HSG results into more pregnancies leading to live births when compared to tubal flushing with ExEm-foam during HyFoSy, and whether this approach...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ovarian and fallopian tube disorders
Study type	Observational invasive

Summary

ID

NL-OMON53875

Source
ToetsingOnline

Brief title
FOil Study

Condition

- Ovarian and fallopian tube disorders

Synonym
Tubal flushing, tubal patency testing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: HSG, HyFoSy, Infertility, Oil-based contrast fluid

Outcome measures

Primary outcome

The primary outcome is pregnancy leading to live birth within six months after randomization. Pregnancy is defined as a positive pregnancy tests or a pregnancy shown on ultrasonographic examination. Live birth is defined as the birth of live baby born beyond 24 weeks of pregnancy.

Secondary outcome

- Time to pregnancy leading to live birth. Calculated from the day of randomization till the first day of the last menstrual bleeding.

- Number of clinical pregnancies, miscarriages, ectopic pregnancies, multiple pregnancies, still births. All within 6 months after randomization.

- Number of adverse events within one months after tubal patency testing, e.g. infection, intravasation, thyroid dysfunction.

- Procedural pain scores, measured by Visual Analogue Scale (VAS) immediately after tubal patency testing.

- Number of fertility treatment cycles (IUI, IVF, ICSI) within 6 months after randomization.

- Number of pregnancy complications, e.g. pregnancy induced hypertension, fetal

growth restriction.

- Neonatal outcomes, e.g. date of birth, sexes, birth weight.

- Quality of life, using EQ-5D-5L questionnaire measured 6 months after randomization.

- Cost-effectiveness, the effectiveness (pregnancies leading to live births) compared to the costs (including costs from a healthcare perspective (costs for tubal patency testing and fertility treatment) and costs from a societal perspective using the iMedical Productivity Costs Questionnaire (iMPCQ)) for both tubal flushing strategies.

Study description

Background summary

We hypothesize that tubal flushing with oil-based contrast during HGS leads to more live births compared to tubal flushing with ExEm-Foam during HyFoSy in infertile women with indication for tubal patency testing. If more live births are achieved, expensive fertility treatments will be less needed, which makes tubal flushing with oil-based contrast during HSG a cost-effective strategy.

Study objective

The main objective of this study is to determine whether tubal flushing with oil-based contrast during HSG results into more pregnancies leading to live births when compared to tubal flushing with ExEm-foam during HyFoSy, and whether this approach is cost-effective. In this study we will also compare the safety of both strategies.

Study design

We plan a multicenter randomized controlled trial with an economic analysis alongside it. Women with indication for tubal patency testing will be randomized to tubal flushing with oil-based contrast during HSG and tubal flushing with ExEm Foam during HyFoSy.

Study burden and risks

As we compare two tubal flushing strategies (tubal flushing with oil-based contrast during HSG and tubal flushing with ExEm-foam during HyFoSy) that are already applied in current practice, no additional risks or burdens are expected from the study. Women are asked to fill in three to five questionnaires. One questionnaire to measure quality of life at baseline (day of randomization) and six months after randomization. One questionnaire to measure indirect (from a societal perspective) costs six months after randomization. Follow-up data can be obtained by a follow-up questionnaire six months after randomization and if applicable two months post-partum, if these data is not reported in their medical files.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Infertile women or women with oligo-or anovulation
- Aged between 18 and 42 years
- With indication for tubal patency testing during the fertility work-up
- Sufficient understanding of the Dutch or English language
- Signed informed consent

Exclusion criteria

- Severe male factor with a total motile sperm count <3x106ml (pre-washed) - Known contrast (iodine) allergy - Women who have had a gynecologic procedure within the last 30 days - Women with known or suspected reproductive tract neoplasia

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2023
Enrollment:	1102
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL83352.018.22