Is Hysterosalpingo-Foam Sonografie (HyFoSy) een kosteneffectief alternatief voor hysterosalpingografie (HSG) als tubadoorgankelijkheidstest in subfertiele vrouwen?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28335

Source
Nationaal Trial Register

Brief title
FOAM Study

Health condition

- Tubal patency testing
- Subfertile women
- Hysterosalpingo-foam sonography (HyFoSy)
- Hysterosalpingography (HSG)
- Cost-effectiveness

- Tubadoorgankelijkheidstest
- Subfertiele vrouwen
- Hysterosalpingo-foam sonografie (HyFoSy)
- Hysterosalpingografie (HSG)
- Kosteneffectiviteit

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: ZonMW
IQ Medical Ventures

Intervention

Outcome measures

Primary outcome

The primary outcome is ongoing pregnancy rates leading to live birth within 12-months after inclusion.

Secondary outcome

The secondary outcomes are:
- Time to pregnancy
- Clinical pregnancy rate
- Miscarriage rate
- Multiple pregnancy rate
- Preterm birth rate
- Concordance between HyFoSy and HSG
- Direct and indirect costs
- Pain scores

Study description

Background summary

OBJECTIVE: To investigate if tubal patency testing during the fertility work-up by hysterosalpingo-foam sonography (HyFoSy) is more cost-effective compared to hysterosalpingography (HSG).

HYPOTHESIS: We hypothesize that HyFoSy has comparable diagnostic accuracy as HSG for a 50% lower cost.

STUDY DESIGN: We plan a multicenter prospective study of women undergoing tubal patency testing by HyFoSy and HSG in a random order during fertility work-up (RCT1). Women in this study with discordant test results will be randomized for management strategy based on HyFOSy or HSG resulting in a diagnostic laparoscopy with chromopertubation (DLS) or an management based on the prognostic model of Hunault (RCT2). Data will be used in a model

based cost-effectiveness analysis.

STUDY POPULATION: Subfertile women scheduled for tubal patency testing.

INTERVENTIONS: Fertility work-up based on HyFoSy.

STANDARD INTERVENTION TO BE COMPARED TO: Fertility work-up based on HSG.

DESIGN: Women will undergo HyFoSy as well as HSG in a random order. Participants with discordant tests results (and therefore apply for different clinical treatments depending on which test was used), will be randomized for for a management strategy based on HyFoSy or HSG resulting in a DLS or a management based on the prognostic model of Hunault. From these data a strategy of outpatient tubal patency testing based on the new technique HyFoSy will be compared with a strategy of tubal patency testing based on HSG.

OUTCOME MEASURES: Ongoing pregnancy rates within 12 month after inclusion. Costs and effectiveness will be analyzed.

SAMPLE SIZE: We propose a non-inferiority effectiveness trial. Under the assumption of a 7% discordance rate between the results of HyFoSy and HSG, we need to randomize 82 women (power 80%) to demonstrate the non-inferiority of HyFoSy (difference < 2%). Basedon the anticipated 7% discordance rate we need to include a total of 1163 women in the study.

COST-EFFECTIVENESS ANALYSIS/BUDGET IMPACT ANALYSIS: The average costs and effectiveness of a strategy of tubal patency testing during fertility work up by HyFoSy or HSG as first line test will be compared. Fertility treatment and pregnancy outcomes will be evaluated after a follow-up of 12 months. Assuming that 20.000 HSGs are made annually in the Netherlands and a difference in cost of €100 in favor of HyFoSy, the budget impact will estimates a saving of over €2 million in case of non-inferiority.

TIME SCHEDULE: month 1-3: preparation; month 4-33 inclusion and follow- up; month 34-36 data analyses and reporting.

Study objective

We hypothesize that a strategy of tubal patency testing during the fertility work-up by HyFoSy results in equal diagnostic outcomes and subsequent management decisions, which lead to similar ongoing pregnancy rates as a strategy of tubal testing by HSG, but tor lower cost.

Study design

Primary outcome: 12 months after inclusion
Quality of life questionaires: one day before randomisation, and after 3, 6 and 12 months after inclusion.

Intervention

RCT1: Hysterosalpingo-foam sonography (HyFoSy) and hysterosalpingography (HSG) in a random order. In case of discordance test results between HyFoSy and HSG women will be included in RCT 2: management strategy based on HSG or HyFoSy resulting in a diagnostic laparoscopy with chromopertubation or an management according to the prognostic model of Hunault. <1x10^6/ml

Contacts

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Eligibility criteria

Inclusion criteria

- Between 18-41 years

- Subfertile for at least one year.

- Valid indication for patency testing in the fertility work-up or before intra-uterine insemination treatment.

Exclusion criteria

- Anovulation not responding on ovulation induction

- Endometriosis

- Tubal patency testing in the past

- Severe male factor with a Total motile sperm count <1x106/ml

- Known contrast (iodine) allergy

- If not willing or able to sign the informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2015
Enrollment:	1163
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-08-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47620
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4587
NTR-old	NTR4746
CCMO	NL50484.029.14
OMON	NL-OMON47620

Study results

Summary results
Study protocol publication: J. van Rijswijk, N. van Welie, K. Dreyer et al., “Te FOAM study: is Hysterosalpingo foam sonography (HyFoSy) a cost-effective alternative for hysterosalpingography (HSG) in assessing tubal patency in subfertile women? study protocol for a randomized controlled trial for a randomized controlled trial,” BMC Womens Health, vol. 18, no. 64, 2018.