

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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 test results (and therefore apply for different clinical treatments depending on which test was used), will be randomized 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 months 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  $< 2\%$ ). Based on 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 estimate 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 for lower cost.

## **Study design**

Primary outcome: 12 months after inclusion

Quality of life questionnaires: 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.  $<1 \times 10^6/\text{ml}$

## Contacts

### Public

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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  $<1 \times 10^6/\text{ml}$
- 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.