

# Is Hysterosalpingo-Foam Sonography (HyFoSy) a cost-effective alternative for hysterosalpingography (HSG) in assessing tubal patency in subfertile women?

Published: 23-12-2014

Last updated: 15-05-2024

The objective of this study is to assess the costs and effects of two strategies of tubal testing during the fertility work-up, one based on the new technique hysterosalpingo-foam sonography (HyFoSy) (innovative strategy) and the other on...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ovarian and fallopian tube disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47620

### Source

ToetsingOnline

### Brief title

Foam study

### Condition

- Ovarian and fallopian tube disorders
- Obstetric and gynaecological therapeutic procedures

### Synonym

testing if the fallopian tubes are open, 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, Goodlife, IQ Medical Ventures

## Intervention

**Keyword:** - Cost-effectivity, - Tubal patency test, -Hysterosalpingo-Foam Sonography (HyFoSy), -Hysterosalpingography (HSG)

## Outcome measures

### Primary outcome

Ongoing pregnancy rates leading to live birth within 12-months after inclusion.

### Secondary outcome

- Time to pregnancy
- Clinical pregnancy rate
- Miscarriage rate
- Multiple pregnancy rate
- Preterm birth rate
- Concordance between HyFoSy and HSG
- Sensitivity and specificity of HyFoSy and HSG
- Procedure time of tubal patency test
- Direct and indirect costs
- Preference and pain scores

## Study description

### Background summary

2 - Is Hysterosalpingo-Foam Sonography (HyFoSy) a cost-effective alternative for hys ... 10-05-2025

HSG is the most widely used outpatient tubal test during fertility work-up. It was introduced in 1914 and still serves as an accurate diagnostic test, but it is a painful examination, implies exposure to ionizing radiation and is expensive. If HyFoSy appears to be as accurate as HSG in diagnosing tubal patency with subsequent equal management decisions and pregnancy outcomes as a HSG-based strategy of tubal testing, HSG could be substituted by HyFoSy during fertility work-up. Given the fact that approximately 20.000 HSGs are performed each year in the Netherlands and based on a cost difference between HyFoSy and HSG of  $\approx 100$ , replacing HSG by HyFoSy would result in a health care cost reduction of  $\approx 2$  million annually.

## **Study objective**

The objective of this study is to assess the costs and effects of two strategies of tubal testing during the fertility work-up, one based on the new technique hysterosalpingo-foam sonography (HyFoSy) (innovative strategy) and the other on hysterosalpingography (HSG) (conventional strategy).

## **Study design**

This is a multicenter prospective study with two embedded RCTs. (Bossuyt et al., 2000). We plan that 1163 women scheduled for tubal testing during their fertility work-up will be included in the study. All will undergo both a HyFoSy and a HSG in random order (RCT 1). Women in whom the results of the tubal patency tests (HyFoSy/HSG) show discordance will subsequently be randomised in a second RCT (RCT2) for management based on the results of HSG or management based on the results of HyFoSy. If bilateral occlusion is found by the allocated tubal patency test, management will be a diagnostic laparoscopy with chromopertubation (DLS). In case of unilateral or bilateral patent tubes are found by the allocated tubal patency test, management according to the prognostic model of Hunault will be applied. This means no subsequent invasive diagnostic interventions, but a prognosis (on natural conception) guided management. (Hunault et al., 2005)

## **Intervention**

Hysterosalpingo-foam sonography (HyFoSy) and hysterosalpingography (HSG). In case of discordant test results women will be randomised for a management strategy based on HyFoSy or HSG. If bilateral occlusion is found by the allocated tubal patency test, the subsequent management will be DLS. In case unilateral or bilateral patency is found by the allocated tubal patency test, the subsequent management will be according to the prognostic model of Hunault.

## **Study burden and risks**

Known complications of HSG are pain related to the procedure, risk of post

procedural infection and allergic reaction on iodine. Intravasation of contrast can also result in allergic reactions. If intravasation of contrast medium is detected the procedure will immediately be abandoned. No complications or potential risks after a HyFoSy procedure are reported up till now. In case a women will be randomised for a laparoscopy, risks are related to anaesthesia and surgical intervention (bleeding, infection, pain and visceral damage).

## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1118  
Amsterdam 1081HZ  
NL

### Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1118  
Amsterdam 1081HZ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Women 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
- 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2015
Enrollment:	1163
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	04-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-06-2019
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

ID: 28335  
Source: NTR  
Title:

## In other registers

Register	ID
CCMO	NL50484.029.14
OMON	NL-OMON28335