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

Published: 23-12-2014
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The objective of this study is to assess the costs and effects of two strategiesof tubal testing during the fertility work-up, one based on the new technique hysterosalpingo-foam sonography (HyFoSy) (innovative strategy) and the other on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ovarian and fallopian tube disorders
Study type	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

HSG is the most widely used outpatient tubal test during fertility vvork-up. lt 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. lf 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 vvork-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 ¤100, replacing HSG by HyFoSy would result in a health care cost reduction of ¤2 million annually.

Study objective

The objective of this study is to assess the costs and effects of two strategiesof tubaI 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 tor tubal testing during their fertility work-up will be included in the study.AII will undergo both a HyFoSy and a HSG in random order (RCT 1). Women in whom the results of the tubaI 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 resuts 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 dicordant 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 viseral 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 <1x106/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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50484.029.14
OMON	NL-OMON28335