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

Gepubliceerd: 19-08-2014 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28335

Bron
Nationaal Trial Register

Verkorte titel
FOAM Study

Aandoening

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

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

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: ZonMW
IQ Medical Ventures

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

VUmc - Voortplantingsgeneeskunde, De Boelelaan 1118, PK -1Y 154, 1081 HZ Amsterdam
J. van Rijswijk
Postbus 7057, 1007 MB Amsterdam
Amsterdam
The Netherlands
020-4445277

Wetenschappelijk

VUmc - Voortplantingsgeneeskunde, De Boelelaan 1118, PK -1Y 154, 1081 HZ Amsterdam
J. van Rijswijk
Postbus 7057, 1007 MB Amsterdam
Amsterdam
The Netherlands
020-4445277

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-05-2015
Aantal proefpersonen:	1163
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47620
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.