

# THL study: A multicenter trial comparing the cost-effectiveness of transvaginal hydrolaparoscopy and hysterosalpingography in the work-up for subfertility.

Published: 28-11-2012

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Objectives: The purpose of this study is to assess the costs and effects of THL compared to HSG in a large randomized controlled trial.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39517

### Source

ToetsingOnline

### Brief title

THL-study

### Condition

- Sexual function and fertility disorders

### Synonym

fallopian tube patency test, tubal patency test

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Culdoscopic, Fallopian Tube Patency Tests, Infertility, Surgery, Transvaginal Hydrolaparoscopy

## Outcome measures

### Primary outcome

Main study parameters/endpoints: The primary outcome is cumulative live birth rate at 24 months.

### Secondary outcome

Secondary outcomes are time to live birth, pregnancy outcome (on-going pregnancy, miscarriage, multiple pregnancy), complications, diagnostic accuracy, generic quality of life, pain and discomfort, patient preferences and costs.

## Study description

### Background summary

Rationale: Infertility or involuntary childlessness is one of life's great misfortunes that affects approximately one in ten couples that aim for conception. Together with poor semen quality and anovulation, tubal pathology ranks among the most frequent causes of subfertility. From the 15,000 couples presenting with subfertility each year, approximately 3,000 will have tubal pathology.

To diagnose tubal pathology various diagnostic tests are available. Hysterosalpingography (HSG) and diagnostic laparoscopy are established invasive tests. Recently, transvaginal hydrolaparoscopy (THL) was developed. THL has the advantage of direct visualisation of the tubes, but in contrast to diagnostic laparoscopy, the procedure can be performed in an outpatient setting. Although THL seems promising, it is unclear what its effectiveness and costs

are relative to the current best imaging strategy, HSG.

### **Study objective**

Objectives: The purpose of this study is to assess the costs and effects of THL compared to HSG in a large randomized controlled trial.

### **Study design**

Study design: Multicenter randomized controlled clinical trial.

### **Intervention**

Intervention: Women will be randomly allocated to THL or HSG.

### **Study burden and risks**

As we compare strategies that are already applied in current practice, no additional risks or burdens are expected from the study.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* Women presenting with primary or secondary subfertility for at least 12 months
- \* Age >18 years
- \* Normal transvaginal ultrasound, performed in the follicular phase of the menstrual cycle
- \* Presence of both ovaries

### Exclusion criteria

- \* Positive Chlamydia status at PCR
- \* Prior tubal testing
- \* Immobile uterus not allowing THL
- \* Women with a uterus in retroversion flexion, as a THL is not feasible in these women
- \* Masses/or cysts in the pouch of Douglas or ovarian cysts, interfering with THL
- \* Prior tubal surgery
- \* Iodine allergy

## Study design

### Design

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):	15-06-2013
Enrollment:	1330
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-12-2013
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

No registrations found.

### In other registers

Register	ID
CCMO	NL41088.018.12