

# Water-versus oliehoudend contrast voor het baarmoederonderzoek.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23300

### Source

Nationaal Trial Register

### Brief title

H2Olie studie

### Health condition

Subfertility, tubal patency testing

## Sponsors and support

**Primary sponsor:** VU University Medical Centre

**Source(s) of monetary or material Support:** zelfgefinancierd

## Intervention

## Outcome measures

### Primary outcome

Ongoing pregnancy defined as registered heartbeat on ultrasound beyond 12 weeks of gestation within the first 6 months after randomisation.

### Secondary outcome

Clinical pregnancy, defined as an ultrasound visible gestational sac.

Miscarriage, defined as a spontaneous loss of pregnancy

Ectopic pregnancy, defined as an embryo implants outside the uterine cavity.

Pregnancy leading to live birth

Live birth, defined as the birth of at least one living child.

Pain scores after the procedure.

Cost calculations of OSCM / WSCM and assisted reproductive technology (ART) treatments.

## Study description

### Background summary

In the evaluation of female subfertility, hysterosalpingography (HSG) is an important examination because of its diagnostic value. The procedure delineates the uterine cavity contours and the rugation and the patency of the fallopian tubes. Since the introduction of HSG as a diagnostic test, various contrast media have been used, from water-soluble to oil-soluble, ionic to nonionic, and high osmolality to low osmolality.

A possible therapeutic effect of diagnostic tubal patency testing has been debated in the literature for more than 50 years.

There are some small studies that show that flushing with Oil-soluble contrast medium (OSCM) has a significant higher odds ratio of live birth compared to flushing with Water-soluble contrast medium (WSCM). But other small studies showed no significant difference in odds ratio of pregnancy or live births after flushing during HSG examination with OSCM or WSCM.

The purpose of this multi centre, randomised controlled trial, is to determine whether at HSG the use of oil-based contrast media results in higher ongoing pregnancy and live birth rates compared to the use of water-based contrast media.

### Study objective

The primary hypothesis is that flushing of the fallopian tubes is more effective with an oil based contrast medium compared to a water based contrast medium in terms of ongoing pregnancy.

### Study design

6 months post hysterosalpingography.

### **Intervention**

Tubal flushing with oil based contrast medium versus water based contrast medium.

## **Contacts**

### **Public**

Department of Reproductive Medicine<br>  
VU University Medical Center<br>  
PK 6Z K180<br>  
De Boelelaan 1118  
K. Dreyer  
Amsterdam 1081 HV  
The Netherlands  
+31 (0)20 4445277

### **Scientific**

Department of Reproductive Medicine<br>  
VU University Medical Center<br>  
PK 6Z K180<br>  
De Boelelaan 1118  
K. Dreyer  
Amsterdam 1081 HV  
The Netherlands  
+31 (0)20 4445277

## **Eligibility criteria**

### **Inclusion criteria**

1. Age between 18 up to and including 39 years;
2. Subfertility of at least one year;
3. Chlamydia antibody titer (CAT) negative;
4. Low risk of tubal pathology according to the medical history;
5. Valid indication for HSG in the fertility work-up or before intra uterine insemination treatment.

## Exclusion criteria

1. Endocrino-pathological diseases as: PCOS, Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type 1;
2. Known or high risk for tubal pathology, CAT positive;
3. Known contrast (iodine) allergy;
4. Male subfertility defined as a post-wash total motile sperm count  $< 3 \times 10^6$  spermatozoa/ml;
5. If not willing or able to sign the consent form.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	1080
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

Date: 01-02-2012

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 32658

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL3120
NTR-old	NTR3270
CCMO	NL26044.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32658

## Study results

### Summary results

N/A