

# Office hysteroscopy compared to saline infusion sonohysterography: a randomised patient compliance study

<b>Submission date</b> 14/02/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/08/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr F.W. Jansen

**Contact details**  
Leiden University Medical Center  
Department of Gynaecology  
Albinusdreef 2  
Leiden  
Netherlands  
2300 RC  
+31 (0)71 5262871  
F.W.Jansen@lumc.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

## Acronym

BETSI trial

## Study objectives

The patient compliance of bettochi hysteroscopy is equal to the compliance of saline infusion sonography.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Randomised open label active controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

## Health condition(s) or problem(s) studied

Indication for examination of uterine cavity

## Interventions

1. Saline infusion sonography
2. Office diagnostic hysteroscopy according to vaginoscopic technique

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

**Primary outcome measure**

1. Parameters for patients compliance
2. Inconclusiveness of technique

**Secondary outcome measures**

1. Failure rate
2. Complication rate

**Overall study start date**

01/01/2006

**Completion date**

01/04/2007

## **Eligibility**

**Key inclusion criteria**

All patients with an indication for examination of cavum uteri

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

100

**Key exclusion criteria**

1. Former office diagnostic hysteroscopy or saline infusion sonography in the past
2. Contraindication of diagnostic hysteroscopy or saline infusion sonography

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

01/04/2007

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Center**

Leiden

Netherlands

2300 RC

## **Sponsor information**

### **Organisation**

Leiden University Medical Centre (LUMC) (Netherlands)

### **Sponsor details**

Albinusdreef 2

P.O. Box 9600

Leiden

Netherlands

2300 RC

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/027bh9e22>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Leiden University Medical Centre (LUMC) (Netherlands)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2008		Yes	No