

Office hysteroscopy compared to saline infusion sonohysterography: a randomized patient compliance study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19984

Source

NTR

Brief title

BETSI trial

Health condition

Indication: examination of cavum uteri

Sponsors and support

Primary sponsor: Leiden University Medical Center
Albinusdreef 2
2300 RC Leiden
The Netherlands

Intervention

Outcome measures

Primary outcome

1. Parameters for patients compliance;

2. Inconclusiveness of technique.

Secondary outcome

1. Failure rate;
2. Complication rate.

Study description

Background summary

Objective:

To compare saline infusion sonography with 'vaginoscopic' diagnostic hysteroscopy to assess patients compliance.

Patients:

All patients with an indication for examination of the cavum uteri.

Intervention:

Saline infusion sonography versus diagnostic hysteroscopy using the vaginoscopic technique.

Main outcome measures:

Parameters for patients compliance.

Study objective

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

Study design

N/A

Intervention

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

All patients with an indication for examination of cavum uteri.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2006
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	29-12-2005
Application type:	First submission

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

NTR-new

NTR-old

Other

ISRCTN

ID

NL512

NTR554

: N/A

ISRCTN5240400

Study results

Summary results

N/A