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

Submission date Recruitment status Prospectively registered 14/02/2006 No longer recruiting [] Protocol Statistical analysis plan Registration date Overall study status 14/02/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 26/08/2009 Surgery

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number NTR554

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

Study type(s)

Diagnostic

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(s)

- 1. Parameters for patients compliance
- 2. Inconclusiveness of technique

Key secondary outcome(s))

- 1. Failure rate
- 2. Complication rate

Completion date

01/04/2007

Eligibility

Key inclusion criteria

All patients with an indication for examination of cavum uteri

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (Netherlands)

Results and Publications

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?
Results article	results	01/09/2008		Yes	No