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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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Netherlands
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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?
Results article	results	01/09/2008		Yes	No