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Endometrial aspiration before or after Saline Infusion Sonography (SIS) in case of abnormal uterine bleeding: effect on specimen quality

Submission date
27/06/2007

Recruitment status
No longer recruiting

Registration date
27/06/2007

Overall study status
Completed

Last Edited
28/10/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

N/A

Study information

Scientific Title
Endometrial aspiration before or after Saline Infusion Sonography (SIS) in case of abnormal uterine bleeding: effect on specimen quality

Acronym
Endometrial aspiration specimen quality after SIS

Study objectives
The specimen contains less evaluable endometrium after Saline Infusion Sonography (SIS) than before SIS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (METc VUmc) on the 7th September 2005 (ref: 2005/46).

Study design
Randomised, single blinded, controlled, parallel group single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Abnormal uterine bleeding, Saline Infusion Sonography (SIS), endometrial aspiration

Interventions
Saline Infusion Sonography (SIS) and endometrial aspiration are performed with the same catheter in one session. Patients are either allocated to aspiration and subsequent SIS, or to the reverse order.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Quality assessment of aspiration specimen by pathologist. Evaluation of the biopsy was performed by the pathologist immediately after taking the endometrial biopsy.

Secondary outcome measures
Reliability of video SIS-images. The SIS was performed in the same session and was recorded on video.

Overall study start date
01/09/2006

Completion date
01/07/2007

Eligibility

Key inclusion criteria
Patients with abnormal uterine bleeding.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

Total final enrolment
113

Key exclusion criteria
1. Pelvic Inflammatory Disease (PID)
2. Cervical cancer

Date of first enrolment
01/09/2006

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre (VUMC)
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology
Division of Reproductive Medicine
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		22/04/2008	28/10/2021	Yes	No