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	Prospectively registered	
		[] Protocol	
Registration date 27/06/2007	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 28/10/2021	Condition category Urological and Genital Diseases	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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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