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

No registrations found.

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

Summary

ID

NL-OMON21295

Source
NTR

Brief title
Endometrial aspiration specimen quality after SIS

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: : VU University Medical Center, Department of Obstetrics and Gynaecology

Intervention

Outcome measures

Primary outcome

Quality assessment of aspiraton specimen by pathologist.

Secondary outcome

Reliability of video SIS-images.

Study description

Background summary

Abnormal uterine bleeding needs careful evaluation to exclude uterine pathology, particularly endometrial cancer. The combination of Saline Infusion Sonography (SIS) and endometrial aspiration is a reliable tool for evaluating abnormal uterine bleeding. SIS enables visualization of the endometrial surface and measurement of the thickness of the endometrium. Endometrial aspiration has been well established as a safe and accurate technique in diagnosing endometrial cancer. Especially in case of increased endometrium thickness, endometrial biopsy is indicated.
Women with abnormal uterine bleeding often need multiple hospital visits. One of the advantages of combining SIS and endometrial aspiration is that both examinations can be performed with the same catheter in one session. Generally, first SIS is performed and subsequently aspiration. However, the quality of the endometrial sample might be affected by the fluid used to distend the uterine cavity. On the other hand, aspirating first may cause artefacts during SIS as parts of the endometrium may be detached from their basic layer.
In this study the order of investigations on the quality of the endometrium sample is investigated.
Patients with abnormal uterine bleeding are randomly allocated either to aspiration and subsequent SIS, or to the reverse order. All samples are sent to the same pathologist who will evaluate the quality of the specimen.

Study objective

The specimen contains less evaluable endometrium after SIS than before SIS.

Study design

N/A

Intervention

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.

Contacts

Public
Department of Obstetrics and Gynaecology
VU University Medical Center
De Boelelaan 1117
A.J.M. Bij de Vaate
Amsterdam 1081 HV
The Netherlands
+31 20 4443613
Scientific
Department of Obstetrics and Gynaecology
VU University Medical Center
De Boelelaan 1117
A.J.M. Bij de Vaate
Amsterdam 1081 HV
The Netherlands
+31 20 4443613

Eligibility criteria

Inclusion criteria

Patiens with abnormal uterine bleeding.

Exclusion criteria

1. PID;

2. Cervical cancer.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	23-01-2007
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	ID
NTR-new	NL863
NTR-old	NTR877
Other	: N/A
ISRCTN	ISRCTN43875039

Study results

Summary results
N/A