RCT to investigate the quality of the of endometrial sample obtained by aspiration when performed before or after the SIS in postmenopausal women.

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The primary objective is to investigate the quality (whether assessable by a pathologist or not) of the endometrial sample obtained by aspiration when performed directly before or after the SIS in postmenopausal women. Secondary objectives are to...

Ethical review	Approved WMO
Status	Completed
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON43383

Source
ToetsingOnline

Brief title
Endometrial SamPling befoRe or aftEr Saline infusion SOnography

Condition

- Reproductive neoplasms female malignant and unspecified
- Menopause related conditions

Synonym
blood loss after the menopause, postmenopausal bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: door het Máxima Medisch Centrum

Intervention

Keyword: Endometrial sampling, Postmenopausal women, Saline infusion sonography

Outcome measures

Primary outcome

The main endpoint is to investigate the quality of the endometrial samples

obtained before or after SIS to determine whether the order of investigations

is of any influence to the percentages of sufficient endometrial samples

(assessable).

Secondary outcome

Secondary outcomes are to determine whether the order of investigations is of

any influence to the reliability of the SIS images, to determine which

investigation is experienced as the most painful and to determine in which

group one of the procedures has a high failure risk (e.g. stenosis).

Study description

Background summary

Postmenopausal bleeding is a very common complaint and can relate to several benign or malignant conditions. One of the options to perform a complete and minimal invasive work-up for women with postmenopausal bleeding is to combine saline infusion sonography (SIS)and office endometrium sampling by aspiration in one session after prior transvaginal ultrasonography (TVU) shows a thickened endometrium(*4mm). However the effects of the SIS to the quality of the sample and the effects of sampling to the quality of the SIS when combined are unknown in postmenopausal women.

Study objective

The primary objective is to investigate the quality (whether assessable by a pathologist or not) of the endometrial sample obtained by aspiration when performed directly before or after the SIS in postmenopausal women. Secondary objectives are to investigate reliability of sonograpic images of the SIS when performed directly before or after the endometrial sampling, to investigate the incidence and intensity of the pain and to investigate the incidence with reasons of failed procedures.

Study design

Randomized controlled trial in two teaching hospitals in the Netherlands.

Intervention

We will perform a randomised controlled trial comparing two diagnostic work-ups. One group will first receive SISand subsequent office endometrial sampling, and the other group will first receive office endometrial sampling and subsequent SIS, both in one session. For both groups we will use a SIS-catheter to perform the SIS and a Pipelle device to perform endometrial sampling.

Study burden and risks

Both of the procedures are part of the standard diagnostic work-up for postmenopausal bleeding in an outpatient setting, in the current guidelines there is no consensus whether SIS or sampling should be perform first. Both investigations are considered safe and proved to be effective to detect abnormalities in women with postmenopausal bleeding. As only the order of investigations will be investigated, there will be no disadvantages for the subjects. Hypothetically the order of investigations can affect the quality of the sample. Subjects with an inconclusive sample and/or SIS will receive (outpatient) hysteroscopy to avoid missing any diagnosis of cancer. This is in accordance with the present guidelines.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women with postmenopausal bleeding and an endometrial thickness of 4mm>.

Exclusion criteria

Women receiving Hormone Replacement Therapy
Women receiving Tamoxifen
Women with cervical cancer.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-04-2016
Enrollment:	232
Type:	Actual

Medical products/devices used

Generic name:	Pipelle (endometrial sampler)/ SIS catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-03-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-12-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22688
Source: NTR

Title:

In other registers

Register	ID
ISRCTN	ISRCTN43875039
CCMO	NL56373.015.16
OMON	NL-OMON22688