Effectiveness of saline-infused sonography and hysteroscopy in the work-up for postmenopausal bleeding

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SIS and hysteroscopy in the work-up for postmenopausal bleeding will be studied. Cost en medical effectiveness in terms of treatment of the postmenopausal bleeding will be evaluated. To assess which women need saline-infused sonography and/or...

Ethical review	Approved WMO
Status	Pending
Health condition type	Menopause related conditions
Study type	Interventional

Summary

ID

NL-OMON32122

Source
ToetsingOnline

Brief title
POMPOEN

Condition

- Menopause related conditions

Synonym
bleeding after menopause, postmenopausal bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: expectant management, hysteroscopy, postmenopausal bleeding, saline-infused sonography

Outcome measures

Primary outcome

Recurrence of postmenopausal bleeding.

Secondary outcome

What is the added diagnostic informativeness of SIS in the diagnosis of

endometrial polyps using hysteroscopy as the reference standard?

What are the costs of TVS, saline infused sonography, hysteroscopy, as well as

the costs of recurrent bleeding?

Study description

Background summary

Postmenopausal bleeding occurs in approximately 15,000 women per year, and may signal serious underlying medical problems. The Dutch guideline on the work-up for postmenopausal bleeding emphasises diagnosing malignant pathology of the endometrium. Transvaginal sonography is used to measure endometrial thickness, if the endometrial thickness measures more than 4 mm, endometrium aspiration (using a Pipelle) is advocated to rule out or diagnose endometrial carcinoma. when malignancy has been ruled out, it is uncertain whether the work-up should be continued with SIS and/or hysteroscopy (and subsequent polypectomy when an abnormality is detected), if at all. The present proposal will study the costs and effects of these strategies. The proposal will consider medical effectiveness and costs.

Study objective

SIS and hysteroscopy in the work-up for postmenopausal bleeding will be studied. Cost en medical effectiveness in terms of treatment of the postmenopausal bleeding will be evaluated. To assess which women need

saline-infused sonography and/or hysteroscopy, if at all, we will answer the following questions:
What are the cost and effects of the following strategies:
1. no further testing after carcinoma has been ruled out
2. SIS for all patients, and hysteroscopy after abnormal SIS
3. immediate hysteroscopy for all patients
4. targeted selection of patients at increased risk for polyps

Study design

Multicenter randomised trial.

Intervention

Patients will be randomised for a subsequent diagnostic work-up with SIS and hysteroscopy or no further diagnostic work-up. In case the patient is allocated to no diagnostic work-up, she will be send home without further diagnostic tests. She will be instructed to contact the gynaecologists in case of recurrence of vaginal bleeding.

Study burden and risks

In women with postmenopausal bleeding it is unclear whether the work up after excluding malignancy should be continued with SIS and/or hysteroscopy, if at all. The potential benefit of SIS and hysteroscopy could be the detection of intracavitary abnormalities (i.e. polyps) and subsequent resection and thereby decreasing the recurrence of postmenopausal bleeding.
Potential risks associated with SIS and hysteroscopy are uterus perforation, infection and bleeding

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

Patients with postmenopausal bleeding and an endometrial thickness of more than 4 mm measured by transvaginal sonography

Exclusion criteria

Patients in whom cervical cytology or endometrial biopsy shows malignancy and patients in whom endometrial biopsy failed of cannot rule out malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL23522.018.08