Validation study of a novel clinical algorithm in evaluating abnormal uterine bleeding using a Combination of Saline Infusion Sonohysterography (SIS) and endometrial brush biopsy (EMB).

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Primary Objective: To assess whether the combination of Saline Infusion Sonohysterography (SIS) and Endometrial Brush Biopsy (EMB) will create an innovative algorithm for diagnosing corpus uteri malignancy in postmenopausal women suffering from...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON41729

Source
ToetsingOnline

Brief title
SIS+EMB algorithm validation

Condition

- Reproductive neoplasms female malignant and unspecified
- Menstrual cycle and uterine bleeding disorders

Synonym
Abnormal uterine bleeding, Postmenopausal uterine bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: stichting vrouw en onderzoek

Intervention

Keyword: abnormal uterine bleeding, endometrial brush biopsy, saline infusion sonography, Sonosure

Outcome measures

Primary outcome

Main study parameter/endpoint

The main outcome of the research will be the sensitivity, specificity, PPV, NPV

of the new algorithm combining SIS & EMB in women with a TED >4mm, compared to

hysteroscopy in determining uterine malignancies

Secondary outcome

Also the patients* experience (pain, number of visits, economic effects,

efficiency etc) will be recorded using a questionnaire.

Study description

Background summary

Abnormal uterine postmenopausal blood loss is a marker for uterine abnormalities and endometrial cancer. In case a patient presents with this complaint further investigation is necessary. In the past, in all women curettage was performed (preferably under general anaesthesia), to rule out malignancies. With advancing age, the chance of malignancy is increasing. The most common cause of the blood loss was endometrial atrophia. Based on methodologically good studies, a new approach was introduced to reduce unnecessary diagnostic procedures: endometrial thickness measurement. In case of thin endometrium (below 4mm) as measured by ultrasound was small, the chance of malignancy appeared low, atrophia was most likely and no further diagnostic procedures were performed (2-4). Specificity and sensitivity of this measurement was 98 and 97 % respectively. In case of recurrent bloodloss

further diagnostic evaluation was performed by hysteroscopy and histology. In case of thickened endometrium (4mm or more), the endometrium was sampled using micro curettage. This approach has proven to be successful and reliable. However, the introduction of this approach has lead to an increase in hysteroscopies (golden standard). Moreover, the number of unnecessary hysteroscopies is increasing due to inconclusive or incomplete samples.

An alternative diagnostic method is saline infused sonography (SIS) combined with EMB. This has proven to be a safe and reliable way to diagnose intrauterine abnormalities (1,5,6). This ultrasound technique is able to visualize the total endometrium and myometrium. In some aspects it is even more reliable then hysteroscopy. (Pre) malignant abnormalities in the endometrium can be exclusively found (in case of negative sampling results) focally in polyps or other endometrial changes. Combination of SIS and endometrial tissue sampling is complimentary in generally accepted existing algorithms.

Hysteroscopy, which is a costly and time-consuming procedure, can easily be exchanged by the combined EMB and SIS approach as described by Mihm et.al (1). Based on these data and observations, we are planning to perform a combined SIS and EMB prior to hysteroscopy using a new algorithm.
At the end of the study we will evaluate the sensitivity and specificity of this combined approach with the gold standard: hysteroscopy.

Study objective

Primary Objective:
To assess whether the combination of Saline Infusion Sonohysterography (SIS) and Endometrial Brush Biopsy (EMB) will create an innovative algorithm for diagnosing corpus uteri malignancy in postmenopausal women suffering from abnormal uterine bleeding, which may restrict diagnostic hysteroscopies to inconclusive or failed SIS and EMB.

Secondary Objective:
To asses the experience (pain, number of visits, economic effects, efficiency etc) of patients on the Sonosure device for combined SIS and EMB using the questionnaire.

Study design

This study is a Prospective controlled multicentre cohort study, which will be performed in 6 months in 6 Santeon hospitals (Canisius-Wilhelmina Hospital, Nijmegen; Catharina Hospital, Eindhoven; Martini Hospital, Groningen; Medisch Spectrum Twente, Enschede; Onze Lieve Vrouwen Gasthuis, Amsterdam; St. Antonius Hospital, Nieuwegein).

We are testing a new algorithm using the golden standard (hysteroscopy) as a control to avoid the risk of missing abnormalities. The tests done with the Sonosure device will be performed on about 50 patients per institution, coming from there regular cohort of women with postmenopausal uterine bleeding. We think each institution should be able to include 50 patients in this particular population within 6 months.

Study burden and risks

The algorithm we test includes the methods that are currently used. The use, results and risks of these methods are well known and generally accepted. The burden for the patients only lies within the group with a clear diagnosis who would not have undergone a hysteroscopy in the standaard situation.

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

- Abnormal postmenopausal bleeding with a TED of >4mm.
- All women with abnormal postmenopausal bleeding will be informed about the study and asked to agree on participation, in case they do meet the 4mm TED criteria, before sonography is performed.

Exclusion criteria

- TED <=4mm
- Suspected uterine infection
- Suspected intrauterine abnormalities seen on first ultrasound
- Pregnancy
- Pathologic evidence of malignancy
- Being incapacitated

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2016
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	SonoSure
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-03-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL51232.060.14