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

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Uterine cavity evaluation and subsequent resection of endometrial polyps in women with postmenopausal bleeding and endometrial thickness of more than 4 mm will lead to less recurrent bleeding compared to women in whom such is not performed.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24422

Bron
NTR

Verkorte titel
POMPOEN

Aandoening

Endometrial polyps, Postmenopausal bleeding.
In Dutch: Endometrium Poliepen, Postmenopauzaal bloedverlies.

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The recurrence of postmenopausal bleeding.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

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 emphasizes 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 effects of these strategies. The proposal will consider medical effectiveness.

Objective:

SIS and hysteroscopy in the work-up for postmenopausal bleeding will be studied. 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 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.

Intervention:

Patients will be randomised for a subsequent diagnostic work-up with SIS and hysteroscopy or no further diagnostic work-up.

Primary Study parameter:

Recurrence of postmenopausal bleeding.

Doel van het onderzoek

Uterine cavity evaluation and subsequent resection of endometrial polyps in women with postmenopausal bleeding and endometrial thickness of more than 4 mm will lead to less recurrent bleeding compared to women in whom such is not performed.

Onderzoeksopzet

An interim analysis is not planned.

Onderzoeksproduct en/of interventie

Eligible patients will be randomly allocated to undergo saline infused sonography (SIS) and outpatient hysteroscopy. All patients will undergo SIS and hysteroscopy independent of the findings during SIS. In case a polyp is seen at hysteroscopy, immediate resection will be performed.

The control group will receive no further diagnostic work-up.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women with postmenopausal bleeding and an endometrial thickness of more than 4 mm in whom a malignancy is ruled out by office endometrial sampling.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women with postmenopausal bleeding during tamoxifen or arimidex treatment;

2. Women with an endometrial sample containing insufficient material for a reliable diagnosis;

3. Women with suspected malignancy after endometrial sampling or cervical cytology.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	03-12-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2013
NTR-old	NTR2130
Ander register	MEC AMC : 08/177
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A