RCT to investigate the quality of the of endometrial sample obtained by aspiration when performed before or after the Saline Infusion Sonography (SIS) in postmenopausal women

Gepubliceerd: 16-02-2016 Laatst bijgewerkt: 19-03-2025

In this randomised study we will investigate the quality of the endometrial sample obtained by office endometrial sampling when performed before or after the SIS in postmenopausal women. Hypothetically the quality of the sample can be affected by...

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

Samenvatting

ID

NL-OMON22688

Bron
NTR

Verkorte titel
ESPRESSO

Aandoening

Postmenopausal bleeding and a thickened endometrium

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Doel van het onderzoek

In this randomised study we will investigate the quality of the endometrial sample obtained by office endometrial sampling when performed before or after the SIS in postmenopausal women. Hypothetically the quality of the sample can be affected by fluid, when performed after the SIS.

Onderzoeksopzet

The endometrial sample and the SIS will be performed in a outpatient visit. The quality (sufficient for diagnosis) will be determined by a blinded pathologist. The gynaecologist (in training) will evaluate and save the SIS images for a second evaluation.
To evaluate the pain, the gynaecologist(in training) will record VAS scores, during and in between the investigations.

Specific pathological analysis and the second (blinded) evaluation of the SIS images will performed in another session.

Onderzoeksproduct en/of interventie

We will perform a randomised controlled trial comparing two diagnostic work-ups. One group will first receive SIS and 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women receiving Hormone Replacement Therapy.

Women receiving Tamoxifen

Women with cervical cancer.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	11-04-2016
Aantal proefpersonen:	232
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43383
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5568
NTR-old	NTR5690
CCMO	NL56373.015.16
OMON	NL-OMON43383

Resultaten