Weefselonderzoek van het baarmoederslijmvlies

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26300

Source
NTR

Brief title
EIN study

Health condition

Endometrial cancer, endometrial hyperplasia and endometrial intraepithelial Neoplasia (EIN)

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

- What is the accuracy of the EIN diagnosed in an office setting (sampling devices and hysteroscopic biopsies)?

Secondary outcome

- What is the risk of a malignancy after EIN in samples obtained in an office setting (office endometrial sampling as well as hysteroscopy)?
- Do samples obtained in an office setting (office endometrial sampling as well as hysteroscopy) contains sufficient material to diagnose EIN?
- How do EIN and hyperplasia correlate in samples obtained in an office setting (office endometrial sampling as well as hysteroscopy)?
- Do gynaecologist adhere to the current Dutch guideline postmenopausal bleeding (11.2015)

Study description

Background summary

Endometrial tissues used to be classified by the World Health Organisation 1994 hyperplasia classification (WHO94). This classification is based on morphological features of architectural complexity and nuclear atypia. The WHO94 classification has four categories of risk classification for hyperplasia: 1) simple hyperplasia (SH), 2) complex hyperplasia (CH), 3) simple hyperplasia with atypia (SAH), and 4) complex hyperplasia with atypia (CAH).A newer method is classification with the endometrial intraepithelial neoplasia (EIN) system. This system is based on constellation of quantitative morphological measures associated with clonality. The diagnosis of EIN must meet five criteria in a single fragment, including architectural gland crowding, altered cytology, minimum size of 1 mm, exclusion of carcinoma, and exclusion of mimics. The diagnosis of EIN can be summarized as a focus of clustered endometrial glands exceeding a gland to stroma ratio of 1:1, which have altered cytology from the background endometrium, and which comprise a sufficient volume of 1 mm. These pathologic criteria were used to develop three disease categories: 1) benign, 2) endometrial intraepithelial neoplasia, and 3) malignant endometrial disease. One of the major strengths of the EIN system is its correlation to outcome: a biopsy diagnosis of EIN imparts a 45-fold increased risk of progression to carcinoma after the first year. After the diagnosis EIN hormonal treatment or a hysterectomy is advised. Endometrium samples were formally obtained through dilatation and curettage (D&C) for which general anaesthesia is warranted. Nowadays, office endometrium sampling (OES) is the first diagnostic step in women presenting with pre or postmenopausal abnormal uterine bleeding, in women with abnormal ultrasonographic features of the endometrium, in women with abnormal smears and in women with a hereditary increased risk of endometrial cancer, like Lynch syndrome. To our knowledge no study is performed to examine the accuracy of EIN in an OES. Neither is information available on the hazard of finding an endometrium carcinoma within twelve months after the diagnosis of EIN in an OES.
This study is an exploratory observational multicentre prospective clinical cohort study. Women aged 40 years and polder, with any indication for endometrial sampling, visiting the Bravis hospital (Bergen op Zoom),Albert Schweitzer hospital (Dordrecht), Fransiscus Gasthuis (Rotterdam) or the Erasmus MC (Rotterdam) will be asked for consent.

Study objective

Office endometrial sampling is not suitable to diagnose EIN due to the small amount of tissue obtained.

Study design

Since data on the prevalence of EIN in OES was not available we started recruitment without a pre-set of patients needed to include. Interim analyses showed that we need approximately 500 participants to have about 25 EIN diagnosis. Therefor we expect that accrual can stop end 2019.

Intervention

Women with a planned, standard samplig procedure are recruited. No additional interventions are done for the purpose of the study.

Contacts

Public
ErasmusMC Cancer Institute
Lena van Doorn

+31630778464
Scientific
ErasmusMC Cancer Institute
Lena van Doorn

+31630778464

Eligibility criteria

Inclusion criteria

Patients, aged 40 years and older, visiting the outpatient clinic with any indication for endometrial biopsy following the Dutch guidelines and common practice. At the distinction of the gynaecologist samples are either obtained by an office sampling device, or by hysteroscopy.

Exclusion criteria

Age < 40

Not able to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2016
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
All study data will be available on request for systematic reviews and meta analyses. Requests made by physicians and epidemiologists will be granted in a timely matter and shared, obeying our hospital policies.

Ethics review

Positive opinion

Date:	18-03-2019
Application type:	First submission

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
NTR-new	NL7608
Other	METC ErasmusMC, Rotterdam : METC-2015-740

Study results