Pelvic and peripheral steroid levels.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26460

Bron
Nationaal Trial Register

Verkorte titel
Steroid hormone serum-levels Endometrial Hyperplasia Endometrial Carcinoma Postmenopausal women

Aandoening

Steroid hormone serum-levels
Endometrial Hyperplasia
Endometrial Carcinoma
Postmenopausal women
Serumwaarden steroidhormonen
Endometrium hyperplasie
Edometium carcinoom
Postmenopausale vrouwen

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: Maastricht University medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum estrogen, progesterone and androgen levels will be measured in the bloodsamples, with a standard and validated radioimmunoassay (RIA) as used by the clinical chemistry lab of the MUMC. The final pathologic outcome (presence of endometrial cancer, hyperplasia or normal endometrium) will be verified on routine formalin fixed paraffin embedded tissue in the clinical pathology lab. Steroid levels will be correlated with pathological findings.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

It is clear that increased exposure to estrogens is an important part of abnormal endometrial development. Chronic stimulation of the endometrium by estrogens results in increased proliferation of endometrial glands, which will cause the development of hyperplasia. Endometrial hyperplasia can be a precursor stage of endometrial carcinoma. The steroids in the blood produced by the ovary enter the systemic circulation through the ovarian veins towards the caval vein or through the para-uterine vessels towards the uterine vein, passing the uterus on their way. The latter may result in a individual estrogen environment around the uterus. Previous studies found that during the follicular and luteal phase the estradiol concentrations in the blood of the parauterine vessels are significantly higher than the concentrations in the peripheral circulation. The progesteron levels are also significantly different. In postmenopausal women a higher concentration of androgens (androstenedione) was found in the ovarian venous plexus compared to the peripheral circulation5. Androgens play an important role in the estradiol synthesis. More than 40% of endometrial carcinoma incidence can be attributed to excess body wight6. This is due to peripheral conversion of androgens to estrogens in adipose tissue by the aromatase enzym. With the knowledge that estrogen levels in the para-uterine vessels can vary strongly, we hypothesize that women with endometrial hyperplasia and endometrial carcinoma may have aberrant local steroid levels around the uterus.

Objective:

The aim of the study is to investigate the local levels of steroid-hormones compared to the peripheral levels in postmenopausal patients with endometrial hyperplasia, endometrial carcinoma and postmenopausal women without these diseases. This will give more information of the local steroid hormone concentrations and its relations to the development of endometrial abnormalities. The secondairy objective is to look at the relation of the results

with patients’ Body Mass Index (BMI).

Study design:

This study will be a case-control study.

Study population:

The study will include all postmenopausal women who undergo an abdominal hysterectomy at the Maastricht University Medical Centre. There will be three subgroups (a) postmenopausal women with endometrial hyperplasia, (b) postmenopausal women with endometrial carcinoma, and (c) controls (postmenopausal women who undergo an abdominal hysterectomy for other reasons).

Intervention:

The same standard operating procedure will be used in each patient: blood samples (2-3 mL) will be taken from the ovarian vein in the infundibolopelvic ligament, veins in the para-uterine vein in the broad ligament and the antecubital vene in the arm. The bloodsamples will be taken during surgery.

Main study parameters/endpoints:

Measurements will be performed with a standard and validated radioimmunoassay (RIA) as used by the clinical chemistry lab. Local pelvic steroid levels will be compared with peripheral levels within and between the three different groups.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Three blood samples (2-3ml) will be taken during general anaesthesia. There are no extra risks for patients participating in this study. The goal of this study is to find more information about the development of endometrial abnormalities.

Doel van het onderzoek

It is clear that increased exposure to estrogens is an important part of abnormal endometrial

development. Chronic stimulation of the endometrium by estrogens results in increased proliferation of endometrial glands, which will cause the development of hyperplasia. Endometrial hyperplasia can be a precursor stage of endometrial carcinoma. The steroids in the blood produced by the ovary enter the systemic circulation through the ovarian veins towards the caval vein or through the para-uterine vessels towards the uterine vein, passing the uterus on their way. The latter may result in a individual estrogen environment around the uterus. Previous studies found that during the follicular and luteal phase the estradiol concentrations in the blood of the parauterine vessels are significantly higher than the concentrations in the peripheral circulation. The progesteron levels are also significantly different. In postmenopausal women a higher concentration of androgens (androstenedione) was found in the ovarian venous plexus compared to the peripheral circulation. Androgens play an important role in the estradiol synthesis. More than 40% of endometrial carcinoma incidence can be attributed to excess body wight. This is due to peripheral conversion of androgens to estrogens in adipose tissue by the aromatase enzym. With the knowledge that estrogen levels in the para-uterine vessels can vary strongly, we hypothesize that women with endometrial hyperplasia and endometrial carcinoma may have aberrant local steroid levels around the uterus.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

There will be three subgroups:

1. Postmenopausal women with endometrial hyperplasia;

2. Postmenopausal women with endometrial carcinoma;

3. Controls (postmenopausal women who undergo an abdominal hysterectomy for other reasons).

We take 3 blood samples (2-3 mL) during surgery:

1. One sample of the infundibolopelvic vein;

2. One sample of the parauterine vein;

3. One sample of through the intravenous infusion.

The steroid concentrations (estrogens, progesterone, androgens) in these samples will be

compared within patients and between different patient groups to study the relation in the development of endometrial abnormalities.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All postmenopausal women planned to undergo an abdominal hysterectomy with bilateral salpingo-oophorectomy. Patients must meet the following criteria:

1. Have at least one ovary before entering the study;

2. Are willing to consent to the collection and storage of blood for this study;

3. Signed informed consent form according to national/local regulations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with known abnormalities in the steroid metabolism;

2. Patients who receive hormone replacement therapy;

3. Patients with any disorder making it impossible to give informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34624
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2222
NTR-old	NTR2347
CCMO	NL31494.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34624

Resultaten

Samenvatting resultaten
N/A