Pelvic and peripheral steroid levels.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26460

Source
NTR

Brief title
Steroid hormone serum-levels Endometrial Hyperplasia Endometrial Carcinoma Postmenopausal women

Health condition

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

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Maastricht University medical Center

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Body Mass Index and the relation with steroid-hormone levels.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 34624
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2222
NTR-old	NTR2347

Register	ID
CCMO	NL31494.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34624

Study results

Summary results
N/A