Pelvic versus peripheral steroid levels in postmenopausal patients with and without endometrial hyperplasia or carcinoma.

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON34624

Source
ToetsingOnline

Brief title
Pelvic and Peripheral steroid-hormone levels

Condition

- Reproductive neoplasms female malignant and unspecified
- Gonadotrophin and sex hormone changes

Synonym
abnormalities of the uterine mucosa, endometrial abnormalities

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie & obstetrie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endometrial Carcinoma, Endometrial Hyperplasia, Postmenopausal women, Steroid hormone serum-levels

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.

Secondary outcome

n/a

Study description

Background summary

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 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

The study will be a case-control study with invasive measurements. The inclusion of patients will be planned between 01-05-2010 and 01-10-2010. The treating specialist will inform patients in whom an abdominal hysterectomy with bilateral oophorectomy is planned. Information about this study will be given verbally and with the aid of an information leaflet. Patients are free to participate in the study and their choice will not influence the treatment they receive. Patients will have time to make the decision to participate or not.

In case of participation, we take 3 blood samples during surgery (for details see chapter 7):
1) one sample of the infundibolopelvic vein
2) one sample of the parauterine vein
3) one sample of the intravenous infusion.

Serum steroid levels will be compared to the pathological outcome. The study participation ends when the final pathology results are known. There is no need for follow-up.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All postmenopausal women planned to undergo an abdominal hysterectomy with bilateral salpingo-oophorectomy. Patients must meet the following criteria:
- have at least one ovary before entering the study
- are willing to consent to the collection and storage of blood for this study
- signed informed consent form according to national/local regulations

Exclusion criteria

- Patients with known abnormalities in the steroid metabolism
- Patients who receive hormone replacement therapy

- Patients with any disorder making it impossible to give informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26460
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	In behandeling
CCMO	NL31494.068.10
OMON	NL-OMON26460