

# Steroïde hormonen en eaLocal steroid production (intracrinology) in endometriosis - inter & intra patient variabilityndometriose

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there exist intra & inter patient variability of 17 $\beta$ -HSD-1 and other enzymes involved in the local generation of estrogens

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Uterine, pelvic and broad ligament disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20678

### Source

NTR

### Brief title

ENDRIN

### Condition

- Uterine, pelvic and broad ligament disorders

### Health condition

endometriosis local estrogen metabolism intracrinology

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Maastricht University Medical Centre (azM)

**Source(s) of monetary or material Support:** non-applicable

## Intervention

- Other intervention

## Explanation

## Outcome measures

### Primary outcome

Clinical data (via a case report form) and epidemiological, life style and symptoms data (via a questionnaire) will be collected prospectively. Blood samples will be taken before treatment. During surgery endometrial and endometriosis biopsies will be collected. Serum and tissue will be analysed for the steroid profile (LCMS). Biopsies will be assessed for the levels of the enzymes involved in the local estrogen generation. Steroid metabolism data will be correlated with clinical characteristics and symptomatology in each subject.

### Secondary outcome

non applicable

## Study description

### Background summary

Endometriosis is characterised by the presence of endometrial tissue outside the uterine cavity. This condition affects 10% of women of reproductive age and is associated with a number of distressing symptoms such as dysmenorrhoea, dyspareunia, pelvic pain and sub-fertility, with important economic impacts on the society.

In a recent study, we showed the endometriotic tissue (ectopic) is capable of producing local higher levels of  $17\beta$ -estradiol than the endometrium located inside the uterus (eutopic) because of high level of the enzyme  $17\beta$ -hydroxysteroid-dehydrogenase type 1 ( $17\beta$ -HSD-1) that converts the low-potent estrone into the high-potent  $17\beta$ -estradiol. In addition to our findings, also others showed that  $17\beta$ -HSD-1 can be a potential drug target for endometriosis.

Compounds targeting the  $17\beta$ -HSD type 1 enzyme are close to the first human trials.

To best design future human trials it is important to characterise the intra & inter patient variability of 17 $\beta$ -HSD-1 and other enzymes involved in the local generation of estrogens (e.g. intracrinology).

Objectives: 1) Chart the intracrine metabolism in women with endometriosis, e.g.: determine the steroid content in endometriosis lesions and in the serum; assess the levels of the intracrine enzymes (mRNA and protein) in endometriosis lesions. 2) Chart the intracrine metabolism (as described in Objective 1) in lesions from distinct location in the same patient.

3) Chart the intracrine metabolism (as described in Objective 1) in the normal endometrium of patients with endometriosis and controls. As secondary objectives, intracrine features will be correlated with additional clinical and radiology characteristics (obtained through standard care) and metabolite profile (such as steroids, inflammatory mediators) in urine and peritoneal fluid. Three hundreds (300) patients and 100 control subjects will be recruited for a total of 400 study subjects.

### **Study objective**

there exist intra & inter patient variability of 17 $\beta$ -HSD-1 and other enzymes involved in the local generation of estrogens

### **Study design**

non applicable

### **Intervention**

Blood (10 mL), urine (10 mL) and peritoneal fluid sampling (10 mL) prior to standard care (e.g. surgery, medical treatment). Completing a questionnaire about life-style. Obtaining an eutopic endometrial sample and a control (without disease) peritoneal sample from both patients and controls (sample from endometriosis tissue will be obtained from rest surgical material).

## **Contacts**

### **Public**

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**Scientific**

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## Eligibility criteria

### Age

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

### Inclusion criteria

Cases:

- Being older than 18 year
- Diagnosis of endometriosis (laparoscopically confirmed)
- Being scheduled for elective laparoscopic (or laparotomy) surgery for endometriosis
- Not taking hormonal medications in the previous three months
- Subjects must have signed an approved informed consent

Controls:

- Being older than 18 year
- Being premenopausal
- Having no prior diagnosis of endometriosis

- Not taking hormonal medications in the previous three months
- Being scheduled for any gynaecological surgery like for tubal ligation, for a benign uterine disease, for diagnosis, for laparoscopic hysterectomy and bilateral adnexectomy
- Subjects must have signed an approved informed consent

## **Exclusion criteria**

Cases:

- Being younger than 18 year
- Diagnosis of atypical hyperplasia, other types of cancer
- Previous diagnosis of endometrial carcinoma
- Being under hormonal medication during the three months preceding the sampling
- Pregnancy
- Inability to approve the informed consent form

Controls:

- Being younger than 18 year
- Being diagnosed with a benign ovarian diseases
- Being diagnosed with any malignancy
- Previous diagnosis of endometriosis
- Being under hormonal medication during the three months preceding the sampling
- Pregnancy
- Inability to approve the informed consent form

## **Study design**

## Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Basic science

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-09-2019
Enrollment:	400
Type:	Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Approved WMO	
Date:	28-02-2019
Application type:	First submission
Review commission:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht
	Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

## Study registrations

## Followed up by the following (possibly more current) registration

ID: 55550

Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL7024
NTR-old	NTR7491
CCMO	NL65333.068.18
OMON	NL-OMON55550

## Study results

### Summary results

non applicable