The Role of the Immune System in Endometriosis

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In this pilot study will focus on the question whether it is possible to detect and distinguish specific immune cells which are previously found in endometriotic tissue, in , macroscopically non-affected peritoneum, peritoneal fluid, peripheral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON50014

Source
ToetsingOnline

Brief title
The Role of the Immune System in Endometriosis

Condition

- Reproductive tract disorders NEC

Synonym
Endometriosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endometriosis, immune modelating factors, T-cells

Outcome measures

Primary outcome

The primary study parameter will be the presence of CD4+ and CD8+ T-lymphocytes

in the different tissue samples.

Secondary outcome

Furthermore, we will assess patient factors and characteristics of the

endometriotic lesion on the T-cell infiltration.

Study description

Background summary

Endometriosis has a prevalence of around 10% in females of the reproductive age. A part of the women affected with the disease can have severe symptoms, most of the times varying with the menstrual cycle. The pathogenesis has been researched, creating certain theories, of which the most popular being the regurgitation theory. However, these theories do not explain how endometriosis dodges the immune system and prevails. Research has been done concerning the immune system in such as macrophages, cytokines, natural killer cells and dendritic cells.

Study objective

In this pilot study will focus on the question whether it is possible to detect and distinguish specific immune cells which are previously found in endometriotic tissue, in , macroscopically non-affected peritoneum, peritoneal fluid, peripheral blood and uterine endometrial samples, which are of patients with endometriosis as well.

Study design

The study design is a cross-sectional, within-patient comparative pilot study, The tissue samples will be collected during surgery. These tissue samples will

be stored and analyzed.

Study burden and risks

There will be no direct benefit for the participating women, other than the perspective of the feeling to contribute to extending the knowledge on endometriosis. The biopsy of visually unaffected peritoneum will extend the operation time with 5-10 minutes (related to operations of 120-480 minutes), with minimum risk when collected with sufficient distance to essential organs (<1%).
The sampling of endometrial tissue from the uterus, via the vaginal route can result in infection, bleeding, scarring and damage to the uterus, with a low risk (<1%) . Peritoneal fluid will be collected during the operation with a minimum of risk (<0,1%) and a minimal extension of operation time.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients between 18-56 years with confirmed endometriosis planned for surgical excision of endometriosis
- Patients being able to read and understand the patient information form
- Signed informed consent

Exclusion criteria

- History of an autoimmune disease, specifically hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV), or any other systemic intercurrent disease or condition that might affect the immunocompetence of the patient
- Treatment with systemic highly immunosuppressive therapy (e.g. transplant recipients)
- Use of systemic continuous corticosteroid therapy (e.g. prednisone i.v. or p.o. >7.5 mg/day)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL73656.042.20