# Endometrial immune profiling: a new perspective for pregnancy morbidity risk assessment in systemic lupus erythematosus - a pilot study

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to characterize the endometrial immune environment in patients with SLE

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56787

**Source**
ToetsingOnline

**Brief title**
Endometrial immune profiling in SLE

### Condition

- Autoimmune disorders

**Synonym**
lupus, SLE

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Reumatologie en Klinische Immunologie
**Source(s) of monetary or material Support:** Abel Tasman Talent Program (ATTP) PhD and Ministerio de Ciencia;Tecnología e Innovación (Colombia)

## Intervention

**Keyword:** Endometrial immune profiling, Obstetric complications, SLE

## Outcome measures

### Primary outcome

Differences between immune cell subsets in menstrual blood in SLE compared to

healthy controls

### Secondary outcome

Differences between immune cell subsets in peripheral blood in SLE compared to

healthy controls

MxA levels as marker for interferon production

NET formation

Different cytokine levels in menstrual and peripheral blood

# Study description

### Background summary

Systemic lupus erythematosus (SLE) affect predominantly women of childbearing age. SLE is a heterogeneous autoimmune disease characterized by interferon upregulation and production of autoantibodies (1). SLE have been associated with a higher risk of adverse pregnancy outcomes (APO) like intrauterine fetal death, fetal growth restriction (FGR), preterm birth, low birth weight, and preeclampsia (2). Type I interferon signature and complement activation in peripheral blood have been linked to APO risk in SLE.
The menstrual cycle is governed by a sophisticated interaction involving endometrial cells, immune cells, cytokines and sex hormones. It is known that the endometrial immune environment prepares its immune balance to accept the embryo and facilitates implantation (5). Receptive endometrium is characterized by a slightly pro-inflammatory response, complement cascade pathway activation, and an adequate interaction between extracellular vesicles, endometrial epithelial cells and the blastocyst (6). Therefore, an optimal balance between pro-inflammatory factors and the tolerogenic adaptive immune response in the endometrial tissue is pivotal for subsequent modifications of the luminal

epithelium of the endometrium and proper embryo implantation.
It has been shown that preconceptional disease activity can predict APO in patients with SLE, which stress the importance of remission of the underlying disease. However, not all APO are explained with these preconceptional, disease-related factors. There could be local immune changes in the endometrial environment in patients with SLE that increase the risk for pregnancy complications. Endometrial immune profiling is a new method to analyze the immune cell distribution and cytokine production in endometrial tissue samples or menstrual blood by different techniques such as multiparameter flow cytometry or gene expression analysis. It has already been suggested as a new screening strategy for personalized care for couples with repeated embryo implantation failures using assisted-reproductive therapy (ART).

### Study objective

to characterize the endometrial immune environment in patients with SLE

### Study design

cross-sectional, observational pilot study in patients with SLE.

### Study burden and risks

All patients will receive standard care and treatment during follow up.
Procedures that will be solely done for research purposes are: extra blood withdrawal and collection of menstrual blood during one period. The knowledge generated in this project will be useful to propose innovative and personalized interventions to achieve better pregnancy outcomes in patients with SLE.

## Contacts

**Public**
Selecteer

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**Scientific**
Selecteer

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

SLE patients
- Fulfilling ACR or SLICC or EULAR/ACR criteria for SLE
- No use of hormonal or intrauterine device anti-contraceptive
- Premenopausal
- Written informed consent
- > 18 years old and *wilsbekwaam*

Healthy women
- No systemic autoimmune disease
- No use of hormonal or intrauterine device anti-contraceptive
- Premenopausal
- Written informed consent
- > 18 years old and *wilsbekwaam*

## Exclusion criteria

- Other autoimmune diseases
- History of abnormal uterine cavity, major gynaecological surgery such as hysterectomy or salpingectomy,, endometriosis or previous reproductive-assisted invasive therapy
- Malignancies
- In case of healthy controls: repeated pregnancy loss or known difficulties to become pregnant (infertility)

# Study design

## Design

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|---|---|
| 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: | Recruiting |
| Start date (anticipated): | 01-07-2024 |
| Enrollment: | 40 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 17-04-2024 |
| 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 | NL85601.042.23 |