# Failing maternal-fetal tolerance in SLE: finding the molecular mechanisms behind pregnancy complications

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Primary Objective:Delineate the differences in cellular composition and function at the maternal-fetal interface in patients with SLE compared to healthy women Secondary Objectives:- Establish a novel in-vitro model to study cell-cell interaction at...

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

## Summary

### ID

NL-OMON50311

**Source**
ToetsingOnline

**Brief title**
Mechanisms behind pregnancy complications in SLE

### Condition

- Autoimmune disorders
- Pregnancy, labour, delivery and postpartum conditions

**Synonym**
pregnancy complications in lupus, pregnancy complications in SLE (Systemic Lupus Erythematosus)

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC

**Source(s) of monetary or material Support:** Ministerie van OC&W,Foundation for Research in Rheumatology (FOREUM)

## Intervention

**Keyword:** Autoimmunity, Immunological tolerance, Pregnancy, SLE

## Outcome measures

### Primary outcome

The main study parameters are the differences in the profile and function of

stromal and immune cells from the placenta of healthy pregnancies,

uncomplicated SLE pregnancies and complicated SLE pregnancies.

### Secondary outcome

A secondary study parameter is the establishment of an in vitro organoid-based

model for the maternal-fetal interface.

# Study description

### Background summary

Systemic lupus erythematosus (SLE) predominantly affects women during their childbearing years, whose pregnancies are characterized by a strongly increased risk for potentially life-threatening maternal complications (e.g. pre-eclampsia, placental abruption) and adverse fetal outcomes (e.g. preterm delivery, growth restriction, fetal death). This severely impacts the physical and mental health of women with SLE and their children. To better predict and improve the outcomes of SLE pregnancies, understanding the underlying biological processes is essential.

### Study objective

Primary Objective:
Delineate the differences in cellular composition and function at the maternal-fetal interface in patients with SLE compared to healthy women
Secondary Objectives:
- Establish a novel in-vitro model to study cell-cell interaction at the maternal-fetal interface

- Identify potential peripheral blood biomarkers associated with failing maternal-fetal tolerance

### Study design

This is a prospective cohort study where participants will be asked to participate during the first trimester of pregnancy. Three times during pregnancy, one time <48 hours before delivery, and one time after birth 45 ml extra blood will be drawn and after birth their placenta*s will be collected.

### Study burden and risks

The blood will be drawn simultaneously with the blood drawn for routine patient care. Only if this in exceptional circumstances is not possible will there be an additional blood collection for this study. The placenta will be collected after birth and poses no burden for the participant. Therefore, there is negligible extra risk of participation in this study.

## Contacts

**Public**
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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Age 18 years or older
Antenatal care and delivery in the Department of Obstetrics and Gynecology of Amsterdam UMC
Patients diagnosed with SLE
Signed informed consent

## Exclusion criteria

Persons unable to give informed consent
Healthy controls: diagnosis with systemic inflammatory disease, or malignant disease.
Multifetal pregnancy

# 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

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-07-2022 |
| Enrollment: | 88 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 02-02-2022 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL80125.018.21 |