BioZ - study
Biologics during pregnancy
Immune profiling of peripheral and endometrial immune cells of women with psoriasis treated with biologics

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To identify the effect of psoriasis and the treatment with biologics on the pre-pregnancy uterine immune environment of psoriasis patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON57075

Source
ToetsingOnline

Brief title
BioZ

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
plaque psoriasis, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Leo Foundation

Intervention

Keyword: Biologics, Menstrual blood, Pregnancy, Psoriasis

Outcome measures

Primary outcome

Differences in phenotype and function of immune cells present in the menstrual blood between patients with psoriasis using biologics, patients with psoriasis using methotrexate, patients with psoriasis using only topical medication and healthy controls.

Secondary outcome

Not applicable

Study description

Background summary

For a successful pregnancy a perfect immunological balance is required, because there has to be tolerance towards a fetus which is partly from the father, and at the same time, protection of the mother and fetus against infection. This immunological balance is regulated by immune cells in the uterus.
The immune system is dysregulated in women with psoriasis. This can negatively affect pregnancy outcomes. In addition, it is hypothesized that the increasingly used biologics can interfere in or restore the immunological balance. However, the fundamental mechanisms on how psoriasis and biologics affect pregnancy are unknown. To get more insight in this, a non-invasive method to obtain immune cells from the pre-pregnancy endometrium will be used to study the effect of psoriasis and biologics on the local uterine immune environment.

Study objective

To identify the effect of psoriasis and the treatment with biologics on the pre-pregnancy uterine immune environment of psoriasis patients.

Study design

Characterisation of the immune cells present in menstrual and peripheral blood of patients with psoriasis using biologics, in patients with psoriasis using methotrexate, in patient with psoriasis using topical treatment and healthy controls.

Study burden and risks

The risk associated with this study is minimal.
The patients and healthy controls will be asked for blood withdrawal of 3 tubes (total of 20 mL). The blood withdrawal with be done by qualified personnel. Therefore the risks related to the withdrawal of the peripheral blood will be minimal.
The use of the menstrual cup to collect menstrual blood is safe. However, the use of menstrual cups were associated with an increased risk on expulsion of IUDs, which is why we exclude participants with an IUD from this study . In addition, collection requires some time and effort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients:
In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- Women aged 18-45 year
- Diagnosis of psoriasis
- Using adalimumab, ustekinumab, ixekizumab, guselkumab or methotrexate for at least 6 months, or topical treatment.

Healthy controls:
In order to be eligible to participate in this study, a healthy control must meet the following criteria:
- Women aged 18-45 year

Exclusion criteria

Patients:
A potential patient who meets any of the following criteria will be excluded from participation in this study:
- Use of other birth control than oral contraceptives (i.e., (copper) intra-uterine devices (IUD))
- Immune mediated co-morbidities (e.g., inflammatory bowel disease, rheumatoid arthritis) or diabetes mellitus
- Smoking
- Participants who are not capable of signing the informed consent
Only for patients treated with biologics the following is also applicable:
- Primary indication of biologic is not psoriasis.
- Use of other immunomodulating medication, such as methotrexate, or antidepressants.
Only for patients treated with methotrexate the following is also applicable:
- Primary indication of methotrexate is not psoriasis.
- Use of other immunomodulating medication, such as biologics, or antidepressants.
Only for patients with topical treatment the following is also applicable:
- Use of any systemic medication that is prescribed for psoriasis, such as biologics or methotrexate, or antidepressants.

Healthy controls:
A potential healthy control who meets any of the following criteria will be excluded from participation in this study:
- Use of other birth control than oral contraceptives (i.e., copper intra-uterine device (IUD))
- Use of immunomodulating medication or antidepressants
- Diagnosed with an autoimmune disease or diabetes mellitus
- Known disorder of reproduction
- Smoking
- Participants who are not capable of signing the 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:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	31-10-2024

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL87112.091.24