

# Cytokines, vaginal microbiome and subfertility, a pilotstudy

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|                              |                        |
|------------------------------|------------------------|
| <b>Ethical review</b>        | Approved WMO           |
| <b>Status</b>                | Recruitment stopped    |
| <b>Health condition type</b> | Immune disorders NEC   |
| <b>Study type</b>            | Observational invasive |

## Summary

### ID

NL-OMON42405

### Source

ToetsingOnline

### Brief title

cytokines and subfertility

### Condition

- Immune disorders NEC
- Reproductive tract disorders NEC

### Synonym

idiopathic subfertility

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Fertiliteitscentrum NijBarrahûs

**Source(s) of monetary or material Support:** Ministerie van OC&W,NijBarrahus betaalt dit onderzoek uit eigen middelen

## Intervention

**Keyword:** chronic inflammation, idiopathic subfertility, vaginal microbiome

## Outcome measures

### Primary outcome

It is a pilot study. The primary aim of the study is to see whether there are differences between 5 cytokines and the profile of the vaginal microbiome between the two groups. This will allow to design a next study with sufficient and seize of the patient groups.

Five cytokines have been selected, two will be assessed directly in the blood plasma (sTNF<sup>\*</sup>R1, IL 6) and three will be assessed after LPS challenging and 24 hour whole blood culture (TNF<sup>\*</sup>, IL 10 en IL 12).

Vaginal microbiom.

With the so called ISpro technic in which the spacer area between 23S and 16S gene will be amplified. Extended bacterial profiles will be made without sequencing. It has been shown that based on three different bacterial groups, the quantitative differences and the ratio between these groups, women who concieved after IVF could be distinguished from women whh did not conceive. This study will be used to confirm these findings.

### Secondary outcome

Confirmation of previous results that a well define vaginale microbiome is not compatible with pregnancy

# Study description

## Background summary

Rationale:

Subfertility is commonly associated with a specific chronic inflammation cytokine profile and with a specific profile of the vaginal microbiome. We suggest that the association between these two variables and their association with subfertility will give rise to new opportunities for the treatment of subfertility.

The identification of these specific cytokine and vaginal microbiome profiles may become an important tool in the decision making, whether embarking upon expensive assisted reproductive treatments, due to a poor outcome, should be contraindicated.

## Study objective

The objective of the study is the falsification of the following null hypotheses:

1. The pro-inflammatory status of the innate immune system of normal fertile women and the of women with idiopathic subfertility are not different.
2. The profile of the vaginal microbiome of normal fertile women and the of women with idiopathic subfertility are not different
3. There is no statistical association between the profile vaginale microbiome en de pro-inflammatoire and the status vof the innate immune system

## Study design

open, prospective, descriptive, comparative pilot study.

## Study burden and risks

The burden is small. The study does not demand extra visits to the clinic, Bloodsampling of two 15 cc tubes (on one occasion) and one vaginal swab will be taken just prior to the IUI procedure.

The benefit for future subfertile women may be substantial. In case vaginal microbiome- and cytokine profiling can identify profiles incompatible with pregnancy then treatments as IVF/ICSI or IUI should not be undertaken. Aiming at pregnancy compatible profiles, before embarking upon stressful and expensive modes of subfertility treatments, may become a priority in subfertility care.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Women who would like to become pregnant; age up to 38 years; regular spontaneous cycles of 28 +/- 4 days; no abdominal surgery in history; serum chlamydia IgG negative; BMI \* 30; good oral hygiene

### Exclusion criteria

Chronic intestinal disease; salpingitis/appendicitis in history; fever in the preceding 2 weeks before entering the study; use of antibiotics in the 6 weeks preceding entry of study; low ovarian reserve (FSH > 10 IU/L menstrual cycle day 3, AMH < 1ng/mL)

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| 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:       | Recruitment stopped |
| Start date (anticipated): | 28-07-2017          |
| Enrollment:               | 100                 |
| Type:                     | Actual              |

## Ethics review

|                    |                                                                     |
|--------------------|---------------------------------------------------------------------|
| Approved WMO       |                                                                     |
| Date:              | 16-02-2016                                                          |
| Application type:  | First submission                                                    |
| Review commission: | RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden) |

## 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     | NL54415.099.15 |