

# Subfertility and chronic inflammation

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24178

### Source

NTR

### Brief title

barew

### Health condition

fertility problems  
ongewenste kinderloosheid

## Sponsors and support

**Primary sponsor:** Fertility Center Nij Barrahûs

Heerenveenseweg 99b

8471 ZA Wolvega

Netherlands

**Source(s) of monetary or material Support:** initiator

## Intervention

## Outcome measures

### Primary outcome

association between cytokine profile and subfertility

association between vaginal microbiome and subfertility

are cytokine profiles related to vaginal microbiome patterns?

### **Secondary outcome**

Statistical model to predict which patient variables can be used to quantify the prognosis of subfertility.

## **Study description**

### **Background summary**

In 20 normal fertile and 20 subfertile women visiting Nij Barrahuis, fertility center a bloodsample and a vaginal swab will be taken at one specific moment in their treatment cycle (moment of IUI, scheduled 24-30H after a spontaneous LH surge).

Does cytokine and/or vaginal microbiome determinations reflect a specific profile, which can be attributed to a (low) chronic state of inflammation and therefore to a changed innate immune system?

### **Study objective**

Hypothesis: Subfertility is influenced by (low) chronic inflammation. Cytokine and microbiome profiling can be substantial in detecting the state of chronic inflammation and may thus help in solving subfertility.

### **Study design**

Recruitment will end April 2016.

### **Intervention**

none

Research subjects are treated with IUI (IntraUterine Insemination). After informed consent one time bloodsampling + one vaginal swab will be taken for determinations of respectively cytokines and microbiome profiling.

## **Contacts**

### **Public**

Hoofd Fertiliteitslaboratorium Nij Barrahûs

J.P.W. Vermeiden  
Heerenveenseweg 99b

[default] 8471 ZA  
The Netherlands  
Tel. 0561610030 Of 0646161592

### **Scientific**

Hoofd Fertiliteitslaboratorium Nij Barrahûs

J.P.W. Vermeiden  
Heerenveenseweg 99b

[default] 8471 ZA  
The Netherlands  
Tel. 0561610030 Of 0646161592

## **Eligibility criteria**

### **Inclusion criteria**

women with idiopathic subfertility for a duration of 3 years and more (N=20)

lesbian couple and single mothers seeking to fulfill their childwish, with negative histories of cycle irregularity, STD's,, abdominal surgery. (N=20)

### **Exclusion criteria**

1. free of fever during the past month prior to study entry
2. free of antimicrobial interventions during the past month of study entry
3. positive CAT IgG sampling

## **Study design**

### **Design**

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	40
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL5286
NTR-old	NTR5393
Other	:

## Study results