Cytokines, vaginal microbiome and subfertility, a pilotstudy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	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*R1, IL 6) and three will be assessed after LPS challenging and 24 hour whole blood culture (TNF*, IL 10 en IL 12).

Vaginal microbioom.
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 concievede 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 idiopatic 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 immume 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

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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 hygiëne

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