Bacterial vaginosis and influence on pregnancy in fertility treatments

Published: 27-03-2019
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This study is conducted to discover if bacterial vaginosis is related to the pregnancy rate in couples undergoing assisted reproduction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55711

Source
ToetsingOnline

Brief title
BIFI

Condition

- Bacterial infectious disorders
- Abortions and stillbirth
- Sexual function and fertility disorders

Synonym
discharge problems; Gardnerella

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: DDL laboratorium Rijswijk,researchfonds HMC Bronovo

Intervention

Keyword: bacterial vaginosis, IUI, IVF, pregnancy

Outcome measures

Primary outcome

Ongoing pregnancy rate at 12 weeks

Secondary outcome

1. Biochemical pregnancy

2. Clinical pregnancy rate as defined by ultrasound with fetal heartbeat at

7-weeks gestation

3. Ectopic pregnancy rate

4. Live birth rate

5. Attempts (ET/IUI) until pregnant

6. Preterm delivery (<37 weeks)

Study description

Background summary

Bacterial vaginosis is defined as a dysbiosis of the vaginal microbiome. Bacterial vaginosis (BV) is known to influence some obstetric outcomes, such as preterm delivery. Only few studies investigated the effect of BV on pregnancy among subfertile women, and a few found a negative effect on fecundity.

Study objective

This study is conducted to discover if bacterial vaginosis is related to the pregnancy rate in couples undergoing assisted reproduction.

Study design

This will be a prospective cohort study, patients starting with fertility treatment will be included.

Before starting the treatment a PCR-swab and pH measurement of the vagina will be done, to assess the vaginal flora. Groups will be divided in BV positive and negative.
At time of insemination/oocyte collection a second swab will be done. Pregnancy outcomes are monitored, also when it becomes a miscarriage. If patients are not pregnant or having a miscarriage after the first treatment, a swab will be done at every insemination/oocyte collection/embryo transfer until the patient is pregnant. All patients have a blood hcg test two weeks after insemination or embryo transfer to confirm pregnancy.

Duration of this study is two years, with a follow-up period until live birth.
After inclusion information about the medical history, fertility treatment (months/cycles of treatment until pregnancy) and relevant information about the pregnancy will be collected (miscarriage, preterm delivery, live birth).

When participating patients are symptomatic for BV they will be treated with clindamycin. After treatment a second swab will be done to assess vaginal flora at the next doctors appointment. This subgroup of symptomatic patients will be analysed within the study as well as separately.

Data will be collected in the data management system Castor. Data will be collected by the investigator van den Tweel or a research student.

Study burden and risks

not applicable

Contacts

Public
Haaglanden Medisch Centrum

Bronovolaan 5
Den Haag 2597 AX
NL
Scientific
Haaglanden Medisch Centrum

Bronovolaan 5
Den Haag 2597 AX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients who undergo fertility treatment, IVF/ICSI or IUI.

Exclusion criteria

three miscarriages or more in history
prophylactic antibiotic use
not able to understand English or Dutch

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2019
Enrollment:	200

Type:	Actual

Ethics review

Approved WMO Date:	27-03-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL63452.098.18

Study results

Date completed:	12-08-2022
Actual enrolment:	174