

Bacterial vaginosis and influence on pregnancy in fertility treatments

Published: 27-03-2019

Last updated: 12-04-2024

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

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|------------------------------|--------------------------------|
| 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

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Scientific

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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

CCMO

ID

NL63452.098.18

Study results

Date completed: 12-08-2022

Actual enrolment: 174