ProVag - The effect of oral probiotics intake on the vaginal microbiota composition

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON56325

Source
ToetsingOnline

Brief title
ProVag

Condition

- Reproductive tract disorders NEC

Synonym
low microbiome profile, Subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ArtPred,Winclove

Intervention

Keyword: IVF, Microbiome, Pregnancy, Probiotics

Outcome measures

Primary outcome

We will collect vaginal and rectal swabs at enrolment and at the end of the treatment (after 8 weeks). The main study parameters is determination of the vaginal and gut microbiota using the inter spacer bacterial profiling (ISpro) technique.

Secondary outcome

- Microbiome profile in the vaginal swabs and gut microbiota in in rectal samples

- Pregnancy rate and (time to pregnancy after inclusion, vital pregnancy at 7 weeks of gestation, pregnancy loss, live birth rate) during a 1 year follow-up period

- Vaginal pH

- Microbiome profile determination after 4 and 6 weeks of treatment

Study description

Background summary

Abnormality of the vaginal microbiota (VMB) has been linked to different conditions associated with fertility and contributing to unsuccessful In Vitro Fertilization (IVF) treatment. Innovations in assisted reproduction technologies offer the possibility to monitor VMB profiles in IVF patients in order to identify the best window for IVF treatment and embryo transfer. One such innovation is the ReceptIVFity test. This is a predictive test that assesses the chances of becoming pregnant in women undergoing IVF treatment based on the VMB composition. The test can result in a High, Medium or Low

vaginal profile score. With a High score, the chance of pregnancy following IVF treatment is 52.6%. With a Medium score, the chance is 23.6% which is approximately the normal chance of becoming pregnant after IVF. And a Low score predicts a pregnancy chance of 5.9%. The data suggest that the prevalence of a Low profile among IVF patients is around 30-35%, with profiles naturally switching from Low to Medium or High. Yet, to date limited evidence is available on the effect of active modification strategy to facilitate the modulation from Low to Medium/High profiles in patients undergoing IVF treatment.
Among such patients, opportunities to improve VMB Low profiles could help restore a profile dominated by Lactobacillus species that is supportive for implantation and subsequent pregnancy, ultimately assisting and empowering patients in their journey of having a child.

Study objective

The goal of this study is to elucidate whether oral probiotic treatment change the VMB profile of IVF patients score from Low to Medium/High (based on the ReceptIVFity test), compared to a placebo treatment

Study design

This is a randomized, placebo-controlled, double-blind intervention designed as a proof-of-principle.

Intervention

Participants will randomly receive probiotic or placebo treatment for 8 weeks.

Study burden and risks

Participants are invited for 4 extra visits to the MUMC+ for collection of vaginal and rectal swabs, and will receive probiotic/placebo treatment. The risks of probiotic treatment are low and no serious adverse events have been reported using them, but only minor gastrointestinal complaints such as bloating or flatulence.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18 - 43 years - Primary or secondary infertility with a IVF indication - Non-smoker - Low* VMB profile, as measured by the ReceptIVFity score - Signed informed consent * Definition of ReceptIVFity Low profile (Koedooder R 2019): - Relative Lactobacillus load <20% and/or - Relative L. jensenii load >35% and/or - Presence of G. vaginalis IST1 and/or - Relative Proteobacteria load >28%

Exclusion criteria

- Use of oral/vaginal antibiotics during the 6 weeks before (and up to) enrolment. Antibiotics use during the study does not lead to exclusion, but will be monitored during follow-up visits.
- Use of other oral or vaginal probiotics at enrolment and during the study
- Use of hormonal treatment other than the IVF course
- Pregnant at enrolment
- Genital symptoms at enrolment
- With history of adverse reaction/allergy to any of the content in the probiotic or placebo
- Serious illnesses, hospitalized (or recently hospitalized) or immune compromised, specified to: usage of immune suppressants, immune deficiency disorders and disorders with a disrupted intestinal barrier

- Undergoing Pre-implantation Genetic Testing (PGT)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-12-2024
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-04-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-10-2024
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL81210.068.22