Diagnostic test (ReceptIVFity) for recognition of embryo implantation failure in practice.

Published: 20-06-2017
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Does the test influence a couples decision to refrain from further treatment.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45617

Source
ToetsingOnline

Brief title
Implementation; impact ReceptIVFity test on the decision

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
embryo implantation failure, subfertility

Health condition

subfertiliteit

Research involving
Human

Sponsors and support

Primary sponsor: Voortplantingsgeneeskunde
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: embryo implantation, predictive test, vaginal microbiome

Outcome measures

Primary outcome

To assess the impact of the ReceptIVFity test on a couples decision prior to

treatment.

Secondary outcome

To determine clinical applicability of the test i.e. ease of sampling, the way

it might influence shared decision making, disadvantages vs advantages of the

test, psycho-social impact of the test.

Study description

Background summary

Research has shown that the species composition within the microbiome residing in the urogenital tract is a proxy for survival of an early embryo and successful implantation. Prior to an in vitro fertilization (IVF) or intracytoplasmic sperm injection (IVF-ICSI) attempt, the ReceptIVFity test is able to predict embryo implantation failure in women with an unfavourable microbiome profile with a predictive accuracy of 93.3%.

Study objective

Does the test influence a couples decision to refrain from further treatment.

Study design

Randomised follow up trial.

Intervention

The ReceptIVFity test consists of collecting a vaginal swab and will be analysed by the interspace profiling (IS-Pro) technique. The test result consists of a personal microbiome profile linked to favourable/unfavourable profile associated with embryo implantation failure.

Study burden and risks

The women who are randomized in the 'intervention group' will obtain a vaginal swab by themselves. The test result of this vaginal swab will provide them with insight in their personal vaginal microbiome profile. The predictive accuracy of the test is 93.3%, i.e. women with an 'unfavourable profile' have poor chance (6-7%) to conceive with an IVF/IVF-ICSI treatment. Knowledge about their own microbiome profile can be beneficial, because the couple has the choice to refrain from further treatment.
Participants will fill in a short questionnaire at 3 intervals for follow up.
This questionnaire (lastmeter) provides insight into the overall wellbeing of the patient. The intervention group will also fill in an additional questionnaire (invloedmeter). This questionnaire gives information about how the test result influences the decision to continue or discontinue further treatment.
In addition, a small subgroup (10-12 patients) of the intervention group will be invited for qualitative research. This qualitative research consists of a 30-minute interview with a psychologist to investigate other aspects of the ReceptIVFity test.
The burden en risk of participation may consist of a demotivating effect of an unfavourable test result. Currently there are no therapeutic options available to modulate an unfavorable profile in a favorable profile.

Contacts

Public
Selecteer

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Selecteer

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Indication for an IVF or IVF-ICSI procedure.
- 18 years < age < 44 years
- women before their first, second or third IVF/IVF-ICSI attempt
- willingness to provide a vaginal swab
- willingness to provide informed consent

Exclusion criteria

- Patients who do not speak the Dutch language
- a 4th IVF/IVF-ICSI attempt that is not part of standard care (not reimbursed by the insurer)
- Patients that will start with IVF/IVF-ICSI treatment within 2 weeks (they do not have time to take the results of the ReceptIVFity test into account when making the decision)
- Patients who had any hormone treatment in the last 2 months
- Patients with premature ovarian insufficiency (POI) or within an egg donation program
- Patients with severe psychological or physical complaints prior to the treatment (difficult to distinguish from the effects of IVF/IVF-ICSI treatment)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	303
Type:	Anticipated

Medical products/devices used

Generic name:	ReceptIVFity test
Registration:	No

Ethics review

Approved WMO

Date:	20-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27025
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59726.078.16
OMON	NL-OMON27025