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

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Primary hypothesis: 1. Women with an unfavourable profile will discontinue the IVF/IVF-ICSI treatment earlier or more often than couples who were not tested Secondary hypothesis: 2. Women with a favourable profile will tend to continue IVF/IVF-...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27025

Bron
Nationaal Trial Register

Verkorte titel
Implementation; impact ReceptIVFity test on the decision

Aandoening

vaginal microbiome, predictive test, embryo implantation

Ondersteuning

Primaire sponsor: ZonMw ‘Medische Inspiratorprijs 2016
Overige ondersteuning: ZonMw 'Medische Inspirator 2016'

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the difference in the number of couples that discontinue IVF or IVF-ICSI treatment based on an unfavourable profile and those women who are not tested (the control group).

Toelichting onderzoek

Achtergrond van het onderzoek

Background

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%.

Objective

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

Study design

Randomised follow up trial.

Study population

Women eligible for IVF or IVF-ICSI treatment who are willing to obtain a vaginal swab prior to treatment.

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.

Primary study parameters/outcome of the study

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

Secondary study parameters/outcome of the study

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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 and risk of participation may consist of a demotivating effect of an unfavourable test result. Currently there are no therapeutic options available to modulate an unfavourable profile in a favourable profile.

Doel van het onderzoek

Primary hypothesis:

1. Women with an unfavourable profile will discontinue the IVF/IVF-ICSI treatment earlier or more often than couples who were not tested

Secondary hypothesis:

2. Women with a favourable profile will tend to continue IVF/IVF-ICSI treatment in comparison with the group of untested individuals

Onderzoeksopzet

before, during and after treatment
The first assessment in the intervention group will be after being informed about their test result.

Control group: at intake (medication, logistics, treatment) for patient who will start an IVF attempt for the first time, day of pick up new medication for patient who will start with a second/third IVF/IVF-ICSI attempt.

The second assessment will be at the day of the oocyte retrieval.

The third assessment will be on the day the patients call with the result of the pregnancy test.

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

room Na-1524

Rivka Koedooder
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
+31107033571

Wetenschappelijk

room Na-1524

Rivka Koedooder
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
+31107033571

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	303
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45617
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6442
NTR-old	NTR6620
CCMO	NL59726.078.16
OMON	NL-OMON45617

Resultaten