Artficial insemination with donor sperm: intrauterine or intra cervical insemination?

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In women treated with donor sperm ICI is non inferior as compared to IUI.

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

Samenvatting

ID

NL-OMON25609

Bron
NTR

Verkorte titel
AID

Aandoening

Donor sperm, intrauterine insemination, intra cervical insemination, artificial insemination with donor sperm, AID

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

ongoing pregnancy leading to a live brith

Toelichting onderzoek

Achtergrond van het onderzoek

Background
In the Netherlands, artificial insemination with donor sperm (AID) is widely performed since 1948. To prevent transmission of sexually transmitted diseases such as Human Immunodeficiency Virus (HIV) and Hepatitis B and C), AID is performed with cryopreserved donor sperm even though pregnancy rates per cycle are lower for cryopreserved sperm than for fresh sperm. There are two techniques for insemination for AID; through the intrauterine (IUI) or the intracervical (ICI) route.
Recently, a Cochrane meta-analysis reported intrauterine insemination with controlled ovarian stimulation (IUI-COS) to be more effective then intracervical insemination with controlled ovarian stimulation (ICI-COS) using donor sperm in terms of live birth rate. However, both IUI-COS and ICI-COS were associated with high multiple pregnancy rates of 14.4% and 6.7% respectively. Therefore, in the Netherlands both insemination techniques are used without the addition of controlled ovarian stimulation.In addition, IUI is more expensive than ICI. These higher costs are generated by the costs involved in processing the sperm. IUI costs around 650 Euro per cycle, compared to 150 Euro per cycle for ICI Considering these uncertainties IUI may generate higher costs than ICI for no increase in pregnancies.

Objective
To assess if intracervical insemination with donor sperm is non-inferior to intrauterine insemination.

Study design
Nationial parallel multicenter randomized clinical trial, comparing IUI without controlled ovarian stimulation with ICI without controlled ovarian stimulation.
Study population
Women eligible for insemination with donor sperm.

Intervention [or: Methods]
A maximum of six cycles of IUI or ICI without controlled ovarian stimulation. In the first cycle one group receives IUI and the other group receives ICI. The time horizon will be eight months
Outcome measures
Primary outcome is onging pregnancy rate leading to a live birth.
Secondary endpoints are clinical pregnancy rate, multiple pregnancy rate, pregnancy complications (preterm birth, preeclampsia), direct and indirect costs.

Power/data analysis
Assuming a live birth rate of 40% after six cycles of ICI and IUI, we need 208 women per arm (total 416 women) to demonstrate the non-inferiority of ICI (alpha .05, beta .80)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness The strategies compared are already broadly applied in current practice. No additional risks are expected. There is no benefit for participants, but the results may benefit future women apllying for AID.

Doel van het onderzoek

In women treated with donor sperm ICI is non inferior as compared to IUI.

Onderzoeksopzet

8 months after randomisation

Onderzoeksproduct en/of interventie

6 cycles of IUI or 6 cycles of ICI without the addition of ovarian hyperstimulation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Indications for AID
o Couples with azoospermia
o Couples with failed TESE procedure
o Couples with a partner with a hereditary genetic defect
o Lesbian couples
o Single women
- Regular cycle
- Women with anovulation who become ovulatory after ovulation induction

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Double sided tubal pathology
- women with a history of subfertility, other than male factor
- Women younger than 18 or older than 43 years

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-06-2014
Aantal proefpersonen:	416
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4309
NTR-old	NTR4462
Ander register	METC AMC : 2013_364

Resultaten

Samenvatting resultaten
N/A