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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25609

Source
Nationaal Trial Register

Brief title
AID

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

ongoing pregnancy leading to a live brith

Secondary outcome

1. clinical pregnancy rate
2. miscarriage rate
3. multiple pregnancy rate
4. time to ongoing pregnancy rate
5. pregnancy complications (preterm birth, preeclampsia)
6. direct and indirect costs

Study description

Background summary

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.

Study objective

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

Study design

8 months after randomisation

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2014
Enrollment:	416
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2014
Application type:	First submission

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
NTR-new	NL4309
NTR-old	NTR4462
Other	METC AMC : 2013_364

Study results

Summary results
N/A