Artificial insemination with donor sperm: Intrauterine insemination or intracervical insemination? The AID study

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To determine which insemination technique in AID (IUI or ICI) is more (cost) effective in terms of ongoing pregnancy leading to a live birth.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON47048

Source
ToetsingOnline

Brief title
AID-study

Condition

- Sexual function and fertility disorders

Synonym
Artificial insemination donor sperm

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: AID, donor sperm, intracervical, intrauterine

Outcome measures

Primary outcome

The primary outcome is ongoing pregnancy leading to a live birth within a time

horizon of eight months.

Secondary outcome

1. clinical pregnancy

2. miscarriage

3. multiple pregnancy

4. pregnancy complications (preterm birth, preeclampsia)

5. direct and indirect costs

Study description

Background summary

In the Netherlands, artificial insemination with donor sperm (AID) is widely performed. 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
In the Netherlands different treatment strategies are performed; some clinics perform intrauterine insemination (IUI) and others intracervical inseminations(ICI) route. .
Recently, a systematic Cochrane review 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, high pregnancy rates were reported. In order to prevent mutiple pregnancies international guidelines like the NICE and RCOG advise to perform IUI without the addition of ovarian stimulation.
Studies on the effectiveness of IUI compared to ICI without addition of

controlled ovarian stimulation are scarce, and not based on randomised controlled trials, but also show that IUI is more effective in terms of ongoing pregnancy rate compared to ICI. Therefore, in 2012 we performed a retrospective nationwide cohort study among eight sperm banks in the Netherlands on IUI and ICI without controlled ovarian stimulation in 2009 and 2010. This study showed no difference in ongoing pregnancy rate for IUI compared tot ICI without 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.

Study objective

To determine which insemination technique in AID (IUI or ICI) is more (cost) effective in terms of ongoing pregnancy leading to a live birth.

Study design

A randomised multicentre clinical trial paralleled with an economic analysis alongside it.

Intervention

A maximum of six cycles IUI or ICI without the addition of ovarian stimulation in a time frame of 8 months.

Study burden and risks

The strategies compared are already applied in current practice. No additional risks are expected. Patients will be asked to fill in a questionnaire on side effects. The possible benefit associated with participation is pregnancy in both groups

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all the following 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

A potential subject who meets any of the following criteria will be excluded from participation in tis study:
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2014
Enrollment:	396
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47330.018.13