Pain Assessment of the IVF Needle

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A potential reduction in pain could be obtained by the use of a thinner aspiration needle, 20 Gauge instead of 14 Gauge used right now. This is the reason for setting up a study that looks at the effect on pain perception in women by the use of a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47399

Source
ToetsingOnline

Brief title
PAIN

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
involuntary childlessness, Subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: JBZ

Intervention

Keyword: Follicle aspiration, IVF, Needle, Pain, VAS

Outcome measures

Primary outcome

Primarily there will be a look at the difference in pain scores with the use of a thinner needle.

Secondary outcome

Secondary outcomes were differences in: oocyte quality, total procedure time, follow procedure/fertilization, demand for additional analgesia during the procedure, time to resign after puncture, pain medication days after puncture, possible influence of age and/or weight on pain score, relationship between pain score and indication puncture, impact doctor performing puncture on pain score and whether the *overall* savings for the economy, considering absenteeism, extra medication used, and (next) puncture under general anaesthesia.

Study description

Background summary

Worldwide, 1.5million artificial reproductive technology cycles are performed each year.
Since the first description in the early 80s, ultrasound-guided follicular aspiration is the first choice in the ovum pick-up for artificial reproduction techniques, like IVF and ICSI. While this procedure is safe and effective, it is described as one of the most stressful and painful components of the entire process.
Pain is affected in different ways: use of pain medication, duration of the intervention, practitioner and thickness of the needle. In many countries, the IVF procedure is done under the presence of an anaesthesiologist. The anaesthesiologist will sedate the patient with Propofol during the procedure and the patient is able to go home at the end of the day. In the Netherlands the majority of the IVF procedure will take place on an outpatient basis without the presence of the anaesthesiologist and without the use of Propofol,

after which the patient can go home when she feels ready to go. In the context of pain-reduction, the various factors mentioned above are explored.

Study objective

A potential reduction in pain could be obtained by the use of a thinner aspiration needle, 20 Gauge instead of 14 Gauge used right now. This is the reason for setting up a study that looks at the effect on pain perception in women by the use of a thinner needle and to see if there are related adverse event.

Study design

A randomised controlled trial in women who will undergo their first IVF or ICSI treatment. They will be randomized between a transvaginal ultrasound-guided puncture with the Sense OD 20/17 Gauge needle and a transvaginal ultrasound-guided puncture with the Origio 14 Gauge needle. They*re asked to give a VAS-pain score at four different point during the procedure. In addition, they receive a questionnaire to take home, in which they have to report the pain scores, the use of pain medication and the effect of the puncture on their daily lives during the first 4 days after the procedure.

Intervention

A transvaginal ultrasound-guided puncture with the Sense OD 20/17 Gauge needle or a transvaginal ultrasound-guided puncture with the Origio 14 Gauge needle for ovum pick up.

Study burden and risks

Nature and extent of the burden and risks for the patients will be the same with the aspiration needle we use nowadays.

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

- Indication for IVF/ICSI
- Female age between 18 and 42 years
- Informed consent
- Normal position of the ovaries

Exclusion criteria

- A previous IVF or ICSI treatment
- Endometriosis
- BMI > 35
- Use of painmedication
- OHSS
- Operation in lower abdomen

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2017
Enrollment:	93
Type:	Actual

Medical products/devices used

Generic name:	Aspiration Needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-06-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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: 22904
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51390.028.15
OMON	NL-OMON22904