PAIN study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22904

Source
NTR

Brief title
PAIN trial

Health condition

IVF punction needle VAS pain

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis - Dr. J.W. van der Steeg
Source(s) of monetary or material Support: none - request for unrestricted grant Vitrolife

Intervention

Outcome measures

Primary outcome

Pain score during IVF punction

Secondary outcome

Secondary end-points are the following:

- the effect of needle diameter on oocyte quality

- the effect of needle diameter on the total time of the procedure of oocyte retrieval

- the effect of needle diameter on fertilization and ongoing pregnancy rate

- the effect of needle diameter on the need of extra intravenous sedation

- the effect of needle diameter on the amount of oral analgesia used the days after the procedure

- does age affect the VAS score

- does body weight (Body Mass Index (BMI))affect the VAS score

- is there a relation between VAS score and indication of the procedure

- does the IVF doctor affect the VAS score

- are there overall socio-economical advantages, such as: absence through illness, the use of extra medication/analgesia and oocyte retrievals under general anesthesia

Study description

Background summary

Women undergoing oocyte retrieval in The Netherlands seem to indicate more pain compared to women undergoing oocyte retrieval in other countries. A possible explanation of this is the use of a relative large diameter aspiration needle in our hospital, 16 Gauge. Therefore, we designed a prospective randomized study to evaluate the effect of a needle with reduced diameter on the pain women experience as well as the possible negative side effects, such as oocyte quality.

Study objective

The primary endpoint of this study is to assess the effect of IVF punction needle thickness on the overall pain experience self-assessed and registered by the patient on a visual analogue scale (VAS 0 = no pain to 10 = worst pain one can imagine) during oocyte retrieval.

Study design

T0: before starting the punction

T1: Immediately after the oocyte aspiration

- the VAS score at that time

- the VAS score of the maximum pain during the IVF/ICSI procedure

T2: 5 minutes after the punction

T3: 30 minutes after the punction

T4: day after

T5: 4days after

Intervention

16 G versus 20 G IVF needle in IVF ICSI patients

Contacts

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Eligibility criteria

Inclusion criteria

- Indication for IVF or ICSI

- Age of the woman between 18 and 42 years

- Signed the informed consent

- Normally positioned ovaries

Exclusion criteria

- Previous IVF or ICSI procedure

- Severy endometriosis (Grades III-IV, endometrial thickness on ultrasound > 4 cm or laparoscopically confirmed grades III-IV)

- BMI > 35 kg/m2

- Standard use of analgesia

- Hyperstimulation

- History of surgery in the lower abdomen

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	93
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47399
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5781
NTR-old	NTR6064
CCMO	NL51390.028.15
OMON	NL-OMON47399

Study results

Summary results

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