Patient-controlled remifentanil analgesia during oocyte retrieval for IVF/ICSI procedures.

No registrations found.

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

Summary

ID

NL-OMON26955

Source
Nationaal Trial Register

Brief title
RELIEF study

Health condition

Women undergoing IVF/ICSI procedures
Oocyte retrieval
Pain

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

1. Pain levels and as measured by 0-10 numeric rating scale (NRS);

2. SpO2, heart rate and blood pressure during oocyte retrieval;

3. Pain levels in the first 4 days post-puncture.

A pain intensity score calculated from an average of 12 ratings across 4 days demonstrated adequate reliability and excellent validity as a measure of the average pain. Furthermore, pain scores in the post-puncture period will be monitored using the McGill pain questionnaire.

Secondary outcome

1. Difference in pain between patients with or without endometriosis;

2. Difference in puncture pain between left- and right ovary;

3. Pain predictors including the expected pain levels, anxiety and pre-procedure pain;

4. Pain scores in the first 4 days post-puncture;

5. Level of sedation according to the Ramsey sedation scale;

6. Use of post-puncture pain medication;

7. Pregnancy rate;

8. Treatment costs;

9. Patient satisfaction with the analgesic method.

Study description

Background summary

Oocyte retrieval for in vitro fertilization (IVF) and intracytoplasmatic sperm injection (ICSI) as infertility treatments is commonly obtained by ultrasound-guided, transvaginal puncture of the ovaries, which is unpleasant and painful for the patient. Although most patients tolerate the procedure well, oocyte retrieval may even be associated with severe visceral pain in a small percentage of patients, especially in patients suffering from endometriosis. In the VU University Medical Center, oocyte retrieval is currently performed under intramuscular pethidine analgesia in combination with light, conscious sedation using an oral short-acting benzodiazepine midazolam (Dormicum® 7,5mg). However, the analgesic efficacy of pethidine has only been scarcely investigated and the single-dose regime for pethidine is not always sufficient to provide optimal pain relief during oocyte retrieval. Remifentanil is a

synthetic opioid with an ultra-short half-life characterized by a rapid onset of action and short latency to its peak effect and may be used for patient controlled analgesia. Currently there are no studies available evaluating the use of remifentanil in patient-controlled analgesia during oocyte retrieval. Furthermore, this analgesic technique has only been scarcely evaluated in comparison with intravenous administration of pethidine. The current study therefore aims to compare the analgesic efficacy and safety of remifentanil versus pethidine in the relief of puncture pain during oocyte retrieval.

Study objective

Is patient-controlled analgesia with remifentanil more efficacious and equally safe as pethidine as analgesic strategy during ultrasound guided transvaginal oocyte retrieval.

Study design

N/A

Intervention

Standard therapy will consist of routine conscious sedation with midazolam (7.5 mg per os) and pethidine (2 mg/kg bodyweight i.m.). Both medications will be administered 30 minutes before the puncture procedure. Since the half-life of pethidine is 3-5 hours, post-puncture analgesia will start when patients are at home.

The investigational treatment consists of continuous intravenous remifentanil administration of 0.05 microgram/kg/minute with the possibility of self-administration of a remifentanil bolus with a dosage of 0.5 microgram/kg per bolus and a lock out of 2 minutes. Remifentanil infusion will start 5 minutes before oocyte retrieval. Since remifentanil has a very short half-life, the analgesic effect of remifentanil will disappear within 5 minutes after the end of remifentanil infusion. The remifentanil infusion will therefore be preceded by preemptive administration of diclofenac (50 mg sup.) for treatment of post-puncture pain 60 minutes before the start of oocyte retrieval.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female subjects who undergo elective IVF/ICSI;

2. Age 18-45 years;

3. Informed consent.

Exclusion criteria

1. Not willing to receive analgesia;

2. Allergy for remifentanil or pethidine.

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):	01-05-2010
Enrollment:	78
Type:	Actual

Ethics review

Positive opinion Date:	27-07-2010
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	NL2325
NTR-old	NTR2431
Other	METC VUmc : ANES2010-05
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A