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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26955

Bron
Nationaal Trial Register

Verkorte titel
RELIEF study

Aandoening

Women undergoing IVF/ICSI procedures
Oocyte retrieval
Pain

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female subjects who undergo elective IVF/ICSI;

2. Age 18-45 years;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not willing to receive analgesia;

2. Allergy for remifentanil or pethidine.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2010
Aantal proefpersonen:	78
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-07-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2325
NTR-old	NTR2431
Ander register	METC VUmc : ANES2010-05
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A