Patient-controlled remifentanil analgesia (PCA) during oocyte retrieval for IVF/ICSI procedures

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

Summary

ID

NL-OMON34877

Source
ToetsingOnline

Brief title
RELIEF study

Condition

- Sexual function and fertility disorders

Synonym
fertility procedure, In vitro fertilization

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: IVF/ICSI procedures, oocyte retrieval, patient-controlled analgesia (PCA), remifentanil

Outcome measures

Primary outcome

The major endpoint of our trail is a reduction in pain levels as measured by a

10-point VAS during oocyte retrieval through transvaginal puncture.

Secondary outcome

Secondary endpoint of our trial will be: (if applicable)

-difference between patient with or without endometriosis,

-difference in puncture pain between left- or right ovary,

-pain scores in the first three days post-puncture,

-factors on influence on puncture pain,

-level of sedation,

-level of nausea during analgesia,

-use of post-puncture medication,

-IVF-related success parameters,

-treatment costs,

-patients* satisfaction with the analgesic method.

Other study parameters: (if applicable)

-Patients* demographics

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 intravenous pethidine analgesia in combination with light, conscious sedation using a short-acting benzodiazepine. 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 systemic administration of pethidine. The current study therefore aims to compare the analgesic efficacy and safety of remifentanil versus pethidine in the treatment of puncture pain during oocyte retrieval.

Study objective

The main objective of this open-label, randomized clinical trial is to asses whether patient-controlled analgesia with remifentanil is more efficious and equally safe as pethidine as analgesic strategy during ultrasound-guided transvaginal oocyte retrieval.

Study design

Open-label, randomized clinical trial.
The study will be performed at the VU University Medical Center.
Female patients undergoing IVF/ICSI in the VU University Medical Center will be included.
Female subjects will be recruited by the attending gynaecologist in the period before the IVF/ICSI procedure. The IVF/ICSI procedure will be performed according to routine clinical practice as is performed in the VU University Medical Center.
Informed consent will be asked at least 24 hours before the measurements take place.
Patients will be randomized into one of both analgesic treatment groups before

undergoing the routine oocyte retrieval procedure. After the retrieval procedure, patients will be asked to fill a pain and discomfort diary in the following three days. Medication-related side effects will also be monitored. The study will end when the acquired sample size is reached.

Intervention

The investigational treatment consists of continuous intravenous remifentanil administration of 0.05 microram/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 paracetamol (1 gram per os) in combination with diclofenac (50 mg per os) for treatment of post-puncture pain 60 minutes before the start of oocyte retrieval.

Study burden and risks

There are no serious adverse events expected since all procedures are standard clinical care.

By suppression of puncture pain by pethidine (i.m.) in combination with midazolam the occurrence of drowsiness and nausea may be increased. These risks are however minimal. Moreover, since pethidine is only once provided the analgesic efficacy may be insufficient to relief transvaginal puncture pain.

Remifentanil will be provided through patient-controlled analgesia, which implies the insertion of an intravenous catheter that will be removed after the puncture procedure. Remifentanil may affect blood pressure and SpO2, which will be closely monitored by the attending physician. In case of unexpected SpO2 changes, 100% oxygen will be provided

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

- Female subjects who undergo elective IVF/ICSI
- Age 18-45 years
- Informed consent

Exclusion criteria

- Not willing to receive analgesia
- Allergy for remifentanil or pethidine

Study design

Design

Study phase:	4
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):	01-06-2010
Enrollment:	78
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dormicum
Generic name:	MIDAZOLAM MALEAAT
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Pethidine
Generic name:	PETHIDINE HYDROCHLORIDE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultiva
Generic name:	REMIFENTANIL HYDROCHLORIDE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Voltaren
Generic name:	DICLOFENAC NATRIUM
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	27-04-2010
Application type:	First submission
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
EudraCT	EUCTR2010-019074-32-NL
CCMO	NL31643.029.10