ISRCTN13604391 https://doi.org/10.1186/ISRCTN13604391

Conscious sedation during egg retrieval

Submission date
03/09/2021

Recruitment status
No longer recruiting

Registration date
06/09/2021

Overall study status
Completed

Last Edited
06/09/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In vitro fertilization (IVF) is one of the treatments available for women unable to conceive. It is a four-stage procedure involving ovarian stimulation, oocyte (egg) retrieval, fertilization, and embryo transfer. Transvaginal ultrasound-guided oocyte retrieval is the gold standard technique for egg retrieval, and it may be painful. The pain experienced is caused by the passage of the needle through the vaginal wall and by mechanical stimulation of the ovary.
The procedures are generally short in duration and there is a low level of pain involved. The optimal anesthetic technique during oocyte retrieval should be safe, effective, have few side effects, have a short recovery time, and be nontoxic to the eggs that are being retrieved.
Various types of pain relief for the retrieval procedure have been studied, including conscious sedation, local anesthetics, epidural spinal and general anesthesia, patient-controlled analgesia and acupuncture. Conscious sedation refers to the use of one or a combination of drugs to produce a state of relaxation and pain relief during a medical procedure.
Midazolam is the benzodiazepine of choice in endoscopic procedures owing to its faster onset of action and shorter duration of action than diazepam. Fentanyl is preferred to pethidine because the former is associated with more rapid onset and clearance with less nausea. Combining midazolam with opioids increases the risk of hypoxemia and apnea. Furthermore, adding propofol may cause cardiorespiratory depression. Sedation alone may be sufficient for this procedure as the procedure is done in a short interval and involves low-level procedure-related discomfort and residual discomfort that dissipates very quickly. In addition to that as this procedure is performed as an outpatient, the physician will be more assured of the wellbeing of the patient on discharge and can ensure that the patient's safety is optimal. The aim of this study is to compare methods of conscious sedation during transvaginal ultrasound-guided oocyte retrieval.

Who can participate?
Patients aged 18 to 45 years old undergoing egg retrieval

What does the study involve?
Participants will be randomly allocated into two groups. The study group will receive midazolam 15 minutes before the procedure and the control group will receive fentanyl combined with midazolam 15 min before the procedure. The surgeon who is performing the procedure will rate the adequacy of the pain relief.

What are the possible benefits and risks of participating?
This procedure is performed as an outpatient procedure, the physician will be more assured about the wellbeing of the patient on discharge after the procedure and patient safety may be improved by reducing the use of opioids. Breakthrough pain perceived in the midazolam only group will be treated using Dynastat.

Where is the study run from?
University Malaya Medical Centre (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
February 2021 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Suntharram Krishnasamy, dr.suntharram@hotmail.com
2. Associate Professor Nuguelis Razali, nuguelis@ummc.edu.my

Contact information

Type(s)
Scientific

Contact name
Dr Suntharram Krishnasamy

Contact details
University Medical Malaya Centre
Jalan Profesor DiRaja Ungku Aziz
Kuala Lumpur
Malaysia
59100
+60 (0)379494422
k.suntharram@ummc.edu.my

Type(s)
Scientific

Contact name
Prof Nuguelis Razali

Contact details
University Medical Malaya Centre
Jalan Profesor DiRaja Ungku Aziz
Kuala Lumpur
Malaysia
59100
+60 (0)379494422
nuguelis@ummc.edu.my

Additional identifiers

Protocol serial number
MREC ID NO: 202178-10349

Study information

Scientific Title
Comparing method of conscious sedation during transvaginal ultrasound-guided oocyte retrieval

Acronym
MIFORE

Study objectives
Midazolam alone is non-inferior compared to the combination of midazolam and fentanyl in women undergoing transvaginal oocyte retrieval in vitro fertilisation treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/08/2021, Medical Research Ethics Committee (formerly known as Medical Ethics Committee), University of Malaya Medical Centre (UMMC-MREC Secretariat Office, Level 2, Kompleks Pendidikan Sains Kejururawatan, University Malaya Medical Centre, Lembah Pantai 59100, Kuala Lumpur, Malaysia; +60 (0)3 79498473; ummc-mrec@ummc.edu.my), ref: 202178-10349

Primary study design
Interventional

Study design
Prospective double-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Conscious sedation for women undergoing in vitro fertilisation during oocyte retrieval

Interventions
Ovarian stimulation and oocyte retrieval will be performed according to the standard protocol and based on routine clinical care of the unit.

Both arms of the study will be injected with local anaesthesia (10 ml lignocaine) in the paracervical area lateral and slightly above the reflection of the vaginal mucosa to the cervix. Prior to injection, aspiration will be done to avoid injection of local anaesthesia intravenously.

Randomization will be generated by a random sequence generator, provided by random.org to avoid bias, and labelled on an opaque envelope, which will be taken out from a designated box upon recruitment of the patient, which will determine which arm the patient belongs to.

The study group (Group M) will receive IV midazolam 0.1/mg/kg 15 minutes before the procedure and the control group (Group F) will receive an IV bolus of fentanyl 50 mcg combined with IV midazolam 0.1 mg/kg 15 min prior to the procedure. The medications will be pre-labelled and will be administered by the medical officer in charge of the reproductive unit. The surgeon who is performing the procedure will be blinded and will rate the adequacy of the analgesia. If the patient perceives pain during the intervention, the patient will be given IV Dynastat 40 mg stat dose as per breakthrough protocol.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Midazolam, fentanyl, lignocaine, Dynastat (parecoxib sodium)

Primary outcome(s)
Pain measured using the Visual Analogue Scale (0 - 10) at 15 minutes from awakening

Key secondary outcome(s)
Measured using a questionnaire post-procedure:
1. Nausea Yes/No
2. Vomiting Yes/No
3. Dizziness Yes/No
4. Patient satisfaction with the oocyte retrieval procedure measured using the Visual Numerating Rating Scale (0-10)

Completion date
31/05/2023

Eligibility

Key inclusion criteria
All patients undergoing oocyte retrieval between age 18 to 45 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

Female

Key exclusion criteria
1. Not consented
2. Use of any other kind of analgesia before recruitment to the study
3. Previous history of hypersensitivity to midazolam/fentanyl/dynastat

Date of first enrolment
13/09/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Department Obstetrics & Gynecology, University of Malaya (grow@ummc.edu.my).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	16/08/2021	06/09/2021	No	Yes
Protocol file			06/09/2021	No	No