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The effects of different opioids on emergence from general anesthesia for short gynecological surgery

Submission date
11/01/2016

Recruitment status
No longer recruiting

Registration date
12/01/2016

Overall study status
Completed

Last Edited
12/04/2016

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Dilatation and Curettage (a procedure where tissue is removed from the womb to diagnose or treat certain conditions) and endometrial biopsies (a procedure where a small sample is taken from the lining of the womb to be looked at under a microscope) are increasingly common gynecological (women's reproductive health) procedures. These procedures are usually carried out under a general anesthetic (drugs used to put patients to sleep). It has been found that the type of anesthetic drug used can have an effect on how long it takes for the patient to recover enough to leave the hospital. Two commonly used drugs are fentanyl and remifentanil, which act by causing drowsiness and preventing pain messages from reaching the brain. The aim of this study is to find out whether there is a difference between emergence times (time for the patient to wake up) between the two drugs, and find out which is preferable to patients.

Who can participate?
Adult women who have had minor gynecological surgery (i.e. to take samples from inside the womb).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups are sedated using propofol and midazolam (standard practice). Those in the first group are also given remifentanil at a dose of 1 microgram per kg of weight to sedate them before their procedure. Those in the second group are also given fentanyl at the same dose to sedate them before their procedure. For both groups, if it is necessary to deepen the level of sedation, additional doses of 0.2 microgram per kg of weight can be added. After the surgery, the time until they wake up from their anesthesia is measured in the post-anesthesia care unit, and the time taken until they can be discharged from the post-anesthesia care unit.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to patients taking part in this study, as the anesthetic techniques involved are used in general practice.

Where is the study run from?
Baskent University Konya Research Centre (Turkey)

When is the study starting and how long is it expected to run for?
March 2015 to February 2016

Who is funding the study?
Baskent University Research Fund (Turkey)

Who is the main contact?
Mr Hüseyin Ulaş Pınar
huseyinpinar2002@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Mr Hüseyin Ulaş Pınar

Contact details
Baskent University Konya Research Center
Hocacihan Mah. Saray cad No: 1
Konya
Türkiye
42080
+90 332 257 0606
huseyinpinar2002@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of remifentanil or fentanyl administration on emergence from general anesthesia with mask after dilatation and curettage or endometrial biopsy procedures in ASA I-II patients

Study objectives
Remfentanil provides earlier emergence from general anesthesia when compared with fentanil administration for general anesthesia for short gynecological procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Baskent University Institutional Review Board and Ethics Committee, 01/04/2015, ref: KA 15/93

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
General anesthesia in gynecological prcedures

Interventions
Participants are randomly allocated to one of two groups by computer.

Group 1: Patients are given 0.02 mg/kg midazolam (Dormicum) IV, in addition to IV 1 mcg/kg remifentanil (Ultiva) administered over thirty seconds. Participants are then given 2 mg/kg propofol (Pofol) for anesthesia induction. Additional dosing can be given if required according to the bispectral index guidance (0.3 mg / kg propofol and 0.2 mcg /kg Remifentanil) during the procedure.

Group 2: Patients are given 0.02 mg/kg midazolam (Dormicum) IV, in addition to IV 1 mcg/kg fentanyl (Fentanyl) administered over thirty seconds. Participants are then given 2 mg/kg propofol (Pofol) for anesthesia induction. Additional dosing can be given if required according to the bispectral index guidance (0.3 mg / kg propofol and 0.2 mcg /kg fentanyl) during the procedure.

Participants in both groups are then observed in the post-anesthesia care unit in order to determine emergence time from general anesthesia.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
1. Remifentanil 2. Fentanyl

Primary outcome measure
1. Emergence time from general anesthesia is determined by recording time taken for the patient to open their eyes and provide a verbal answer to a question
2. Discharge time from post-anesthesia care unit is determined according to modified Aldrete score at the time of discharge from the post-anesthesia care unit

Secondary outcome measures
1. Pain is measured using the visual analog scale post-operatively in the post-anesthesia care unit
2. Additional analgesic requirement (if VAS is upper 5 point) post-operatively in the post-anesthesia care unit
3. Patient satisfaction with anesthesia is measured using the visual analogue scale post-operatively in the post-anesthesia care unit
4. Intra-operative dreaming is measured through patient interviews 10 minutes post-operatively

Overall study start date
20/03/2015

Completion date
20/02/2016

Eligibility

Key inclusion criteria
1. Female patients between 18 and 60 years
2. ASA physical status I-II
3. Have undergone dilatation curettage and/or endometrial biopsy procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
128

Key exclusion criteria
1. Psycihiatric disorder
2. Opioid drug abusement

Date of first enrolment
20/04/2015

Date of final enrolment
20/01/2016

Locations

Countries of recruitment
Türkiye

Study participating centre
Baskent University Konya Research Centre
Baskent University Hospital Group
Hoca Cihan Mahallesi Saray Cad. 1
Konya
Türkiye
42080

Sponsor information

Organisation
Baskent University Research Fund

Sponsor details
Bağlıca Kampüsü Eskişehir Yolu 20. km
Bağlıca
Türkiye
06810
+90312 2466679
tip@baskent.edu.tr

Sponsor type
University/education

ROR
https://ror.org/02v9bqx10

Funder(s)

Funder type
University/education

Funder Name
Baskent University Research Fund

Results and Publications

Publication and dissemination plan
Intention to publish results in a peer reviewed journal.

Intention to publish date
31/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request