

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

Submission date 11/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/04/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 remifentanyl, 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 remifentanyl 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 remifentanyl 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
Remfentanyl provides earlier emergence from general anesthesia when compared with fentanyl 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 procedures

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 remifentanyl (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 Remifentanyl) 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. Psychiatric disorder
2. Opioid drug abuse

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