

Bolus Dosing of Remifentanyl with Propofol for Gynaecological Day Case Surgery

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/08/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0203132060

Study information

Scientific Title

Bolus Dosing of Remifentanyl with Propofol for Gynaecological Day Case Surgery

Study objectives

Does general anaesthesia using bolus dosing of remifentanyl with propofol, compared with the alfentanil/propofol/isoflurane technique, for short, day-case gynaecological procedures reduce recovery time and improve time to street-fitness and discharge?

To compare two anaesthetic techniques (remifentanyl/propofol with the commonly used alfentanil/volatile agent based anaesthetic) in the induction and maintenance of anaesthesia in day case gynaecological surgery. To establish if there are clinical advantages of one technique over the other. We aim to disprove the Null Hypothesis. The Null Hypothesis being tested is that there is no difference in recovery time and time to discharge for patients undergoing short, day-case gynaecological procedures under general anaesthesia using either bolus dosing or remifentanyl with propofol or the commonly used alfentanil/propofol/isoflurane technique.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Anaesthesia

Interventions

To study 60 American Society of Anesthesiologists (ASA) 1 and 2 subjects presenting for routine elective minor gynaecological day case surgery. Subjects will be randomised to two groups A and B.

Group A will act as the control group. They will undergo induction of general anaesthesia with alfentanil and propofol and maintenance of anaesthesia with nitrous oxide and isoflurane.

Group B will be the study group. They will undergo induction of anaesthesia using remifentanyl and propofol. Maintenance will be with nitrous oxide and incremental bolus doses of a premixed solution of remifentanyl and propofol.

We will observe several aspects of post-operative recovery such as time to eye opening, recollection of name, resumption of spontaneous respiration, fitness for discharge from

recovery and readiness for home discharge. We will also look at analgesic requirements and the incidence of nausea and vomiting. The allocation to group A or B will be blinded to the investigator noting the outcome data points.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

1. Time from end of procedure to
 - 1.1. eyes open
 - 1.2. recollection of name
 - 1.3. fitness to discharge from recovery
 - 1.4. ready for home discharge
2. post-operative pain
3. analgesic requirements
4. nausea and vomiting
5. total dose of agents used

Secondary outcome measures

Not provided at time of registration

Overall study start date

24/10/2003

Completion date

13/07/2005

Eligibility**Key inclusion criteria**

ASA 1 and 2 subjects presenting for routine elective minor gynaecological day case surgery. All patients attending for surgery will be given a patient information leaflet and those agreeing to participate in the study will be asked to sign a consent form. They will be the subject of therapeutic research.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Patients giving history of reflux or hiatus hernia, obesity or cases requiring tracheal intubation for any other reason.

Date of first enrolment

24/10/2003

Date of final enrolment

13/07/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter

United Kingdom

EX2 5DW

Sponsor information**Organisation**

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Devon and Exeter NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration