ISRCTN27187868 https://doi.org/10.1186/ISRCTN27187868

Bolus Dosing of Remifentanil with Propofol for Gynaecological Day Case Surgery

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/08/2021	Surgery	[ ] 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 Remifentanil with Propofol for Gynaecological Day Case Surgery

Study objectives
Does general anaesthesia using bolus dosing of remifentanil 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 (remifentanil/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 remifentanil 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 remifentanil and propofol. Maintenance will be with nitrous oxide and incremental bolus doses of a premixed solution of remifentanil 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