

# Bolus Dosing of Remifentanyl with Propofol for Gynaecological Day Case Surgery

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/08/2021	<b>Condition category</b> 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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**  
**Royal Devon & Exeter Hospital (Wonford)**  
Exeter  
United Kingdom  
EX2 5DW

## **Sponsor information**

**Organisation**  
Department of Health

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Royal Devon and Exeter NHS Trust (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration