

# A comparison of analgesic efficacy and postoperative nausea and vomiting following morphine or fentanyl for perioperative analgesia in paediatric adenotonsillectomy

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/10/2015	<b>Condition category</b> Signs and Symptoms	<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

### Contact name

Dr AS Carr

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0185088382

# Study information

## Scientific Title

A comparison of analgesic efficacy and postoperative nausea and vomiting following morphine or fentanyl for perioperative analgesia in paediatric adenotonsillectomy

## Study objectives

To determine whether there is a difference in vomiting episodes or analgesic requirements after use of morphine or fentanyl during adenotonsillectomy operation.

## 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

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

## Health condition(s) or problem(s) studied

Signs and Symptoms: Vomiting

## Interventions

Children aged 5-16 years, American Society of Anesthesiologists (ASA) 1-2 scheduled for adenotonsillectomy will be recruited to the study after obtaining parental consent and verbal assent from the child, if appropriate. They will receive a standard anaesthetic. All children will receive paracetamol and diclofenac for analgesia. At induction all children will receive fentanyl. Intraoperatively they will be randomised to receive either morphine intramuscular (IM) (group M) or fentanyl (group F). Postoperatively they will receive fentanyl or morphine as rescue

analgesia. Rescue antiemetic will be given if required. Postoperatively, pain and sedation scores and the number of vomiting episodes in 24 h will be assessed and the intravenous (IV) and oral morphine requirements over 24 h.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Morphine, fentanyl

**Primary outcome measure**

The following outcome measures will be used: pain scores, sedation scores, numbering of vomiting episodes in 24 h, IV and oral opioid requirements in 24 h.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

15/04/2002

**Completion date**

15/04/2003

## **Eligibility**

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

15/04/2002

**Date of final enrolment**

15/04/2003

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**Derriford Hospital**

Plymouth

United Kingdom

PL6 8DH

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Plymouth Hospitals 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