

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 26/10/2015	Condition category Signs and Symptoms	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

15/04/2003

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

Study participating centre

Derriford Hospital

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Plymouth Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration