ISRCTN62811834 https://doi.org/10.1186/ISRCTN62811834

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 [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/10/2015	**Condition category** Signs and Symptoms	[_] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes