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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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
26/10/2015

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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