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Comparison of codeine phosphate and morphine sulphate in infants undergoing cleft palate repair

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 07/08/2008	**Condition category** Surgery	

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
N0190133718

Study information

Scientific Title

Study objectives
To compare two commonly used analgesic regimes, intravenous morphine versus intramuscular codeine, in controlling immediate post-operative pain following surgery for primary cleft palate repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Comparative, randomised, controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cleft palate repair

Interventions
Infants received one of two analgesics intraoperatively for immediate postoperative pain relief. Morphine was given by intravenous injection and codeine by the intramuscular route.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Morphine, codeine

Primary outcome measure

Pain scores in the immediate postoperative period for 2 hours following surgery - is morphine better/same/worse than established regimes?

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/2003

Completion date
01/06/2005

Eligibility

Key inclusion criteria
Infants having primary cleft palate repair with informed parental consent to enter the study.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
30

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/10/2003

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Queen Victoria Hospital NHS Trust
East Grinstead

United Kingdom
RH19 3DZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Queen Victoria Hospital NHS Foundation 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/09/2007		Yes	No