

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

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/08/2008	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
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

Primary study design

Interventional

Study design

Comparative, randomised, controlled clinical study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration.

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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**

United Kingdom

England

Study participating centre

The Queen Victoria Hospital NHS Trust

East Grinstead

United Kingdom

RH19 3DZ

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Queen Victoria Hospital NHS Foundation 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?
Results article	Results	01/09/2007		Yes	No