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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Steven Fenlon

#### Contact details

The Queen Victoria Hospital NHS Trust Holtye Road East Grinstead United Kingdom RH19 3DZ

## 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

#### Study design

Comparative, randomised, controlled clinical study

#### Primary study design

Interventional

#### 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