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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Steven Fenlon

#### Contact details

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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

# 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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleResults01/09/2007YesNo