

Double-blind randomised study into the efficacy of codeine phosphate analgesia after cleft palate repair in infants

| | | |
|--|---|--|
| 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 type="checkbox"/> Results |
| Last Edited 02/11/2016 | Condition category Surgery | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr M R J Sury

Contact details

Anaesthetics
Great Ormond Street Hospital
Great Ormond Street
London
United Kingdom
WC1N 3JH

Additional identifiers

Protocol serial number

N0012128260

Study information

Scientific Title

Double-blind randomised study into the efficacy of codeine phosphate analgesia after cleft palate repair in infants

Study objectives

How effective is codeine phosphate after cleft palate repair in infants and how much is metabolised to morphine in this age group?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cleft palate repair

Interventions

1. Codeine phosphate after cleft palate repair
2. No codeine phosphate

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Codeine phosphate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/2007

Eligibility**Key inclusion criteria**

Children who have cleft palate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2003

Date of final enrolment

31/08/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Great Ormond Street Hospital

London

United Kingdom

WC1N 3JH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Great Ormond Street Hospital for Children NHS Trust/Institute of Child Health

Funder Name

Association of Paediatric Anaesthetists

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration