

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

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes