

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2003

Completion date

31/08/2007

Eligibility

Key inclusion criteria

Children who have cleft palate

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Great Ormond Street Hospital
London
United Kingdom
WC1N 3JH

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

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

Funder Name

Association of Paediatric Anaesthetists

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