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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	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 02/11/2016	**Condition category** Surgery	[ ] Individual participant data [ ] 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

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