

The impact of timing of surgical repair of cleft lip on parent-infant interactions and infant development

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/08/2008	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

G9629970

Study information

Scientific Title

Study objectives

To determine the effects of timing of lip repair on parent-infant relationship and infant development

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Plastic surgery

Interventions

Groups are those having neonatal lip repair, and those having 'late' ie 2-3 month repair

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Parental mental state, mother-infant interactions, infant social and cognitive development

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1997

Completion date

30/09/2000

Eligibility

Key inclusion criteria

Singleton infant, 37-42 week gestation, greater than 2.5 kg birthweight, index group have cleft lip (with or without cleft of palate)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

200

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/1997

Date of final enrolment

30/09/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Winnicott Research Unit

Reading

United Kingdom

RG6 6AL

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/11/2004		Yes	No