

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Professor Lynne Murray

**Contact details**  
Winnicott Research Unit  
Department of Psychology  
University of Reading  
3 Earley Gate  
Whiteknights  
Reading  
United Kingdom  
RG6 6AL

## 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

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

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?
<a href="#">Results article</a>	Results	01/11/2004		Yes	No