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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
25/10/2000		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
25/10/2000	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
07/08/2008	Surgery		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Lynne Murray

#### Contact details

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# Additional identifiers

**Protocol serial number** 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

#### Study type(s)

**Not Specified** 

#### 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(s)

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

# Key secondary outcome(s))

Not provided at time of registration

# 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

## Healthy volunteers allowed

No

#### Age group

Child

#### Sex

All

#### 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

**United Kingdom** 

England

# Study participating centre

Winnicott Research Unit

Reading United Kingdom RG6 6AL

# Sponsor information

## Organisation

Medical Research Council (MRC) (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**

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