

# An investigation of the effects of pre-surgical orthodontics (baby plates) on feeding and speech outcomes in children with cleft lip and /or palate

<b>Submission date</b> 01/03/2001	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/03/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2010	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Anthea Masarei

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

SP3308

# **Study information**

## **Scientific Title**

### **Study objectives**

Added 08/01/2009:

To investigate the controversial assertion that pre-surgical orthopedics (PSO) facilitate feeding in infants with cleft lip and palate.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 07/01/2010:

The Ethics Committee of GOSH and the Institute of Child Health gave approval.

### **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**

### **Health condition(s) or problem(s) studied**

Speech therapy

### **Interventions**

Infants recruited are randomised to be managed with or without baby plates. Minimisation is used to ensure that groups are similar with respect to sex and birth order.

### **Intervention Type**

Other

### **Phase**

Not Applicable

**Primary outcome measure**

Added 08/01/2009:

Measurements were made at 3 months of age (pre-surgery) and at 12 months of age (post-surgery):

1. Anthropometry
2. Oral motor skills

**Secondary outcome measures**

Added 08/01/2009:

1. Objective measures of sucking, collected at 3 months using the Great Ormond Street Measure of Infant Feeding
2. Videofluoroscopic assessment (in 21 participants only)

**Overall study start date**

01/01/2002

**Completion date**

31/12/2005

## Eligibility

**Key inclusion criteria**

Infants born with an isolated cleft of the palate (soft palate and 2/3 of the hard palate) or complete unilateral cleft of the lip and palate and who are referred to the twin site cleft lip and palate centre of St Andrews Centre for Burns and Plastic Surgery and Great Ormond Street Hospital for Children NHS Trust

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

Added 08/01/2009: 50

**Key exclusion criteria**

Added 07/01/2010:

1. Required cardiac surgery
2. Diagnosed at birth with neurological impairment and/or a syndrome known to adversely affect feeding and/or growth

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

31/12/2005

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Speech and Language Therapy Department**

London

United Kingdom

WC1N 3JH

# Sponsor information

## Organisation

Action Medical Research (UK)

## Sponsor details

Vincent House

Horsham West Sussex

United Kingdom

RH12 2DP

## Sponsor type

Charity

## Website

<http://www.action.org.uk/>

## ROR

<https://ror.org/01wcqa315>

# Funder(s)

## Funder type

Charity

## Funder Name

Action Medical Research (UK)

**Alternative Name(s)**

actionmedres, action medical research for children, AMR

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**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	01/03/2007		Yes	No