

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

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### Contact details

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## Additional identifiers

### Protocol serial number

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.

### Primary study design

Interventional

### Study design

Randomised controlled trial

### Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s)

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Speech and Language Therapy Department

London

United Kingdom

WC1N 3JH

# Sponsor information

## Organisation

Action Medical Research (UK)

## ROR

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

# Funder(s)

## Funder type

Charity

## Funder Name

Action Medical Research (UK)

## Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/03/2007   |            | Yes            | No              |