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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
01/03/2001		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/03/2001	Completed	[X] Results		
<b>Last Edited</b> 07/01/2010	Condition category Oral Health	[] 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.

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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?
Results article	results	01/03/2007		Yes	No