

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

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?
Results article	results	01/03/2007		Yes	No