

Is a one stage or two stage cleft palate repair more beneficial in children with complete one sided cleft palate defects with respect to speech development and palatal fistula formation?

Submission date 16/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 31/05/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/11/2020	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims:

A cleft is a gap or split in the upper lip, the roof of the mouth (palate) or both. Cleft lip and/or palate is a common facial abnormality which begins during development in the womb. In India, about 1 in every 1,000 children are affected by this birth defect. These children usually have difficulties in speaking, social integration and psychological (mental) adjustment, because of their deformity. There are different techniques that have been developed to treat cleft palate defects. The timing and stages of cleft palate repair are also varied. Some surgeons follow a one-stage repair protocol, which involves correcting the deformity in a single operation. Others however perform the repair in two stages, which involve operations when children are aged 12-13 months and 24-25 months. The aim of this study is to compare the effectiveness of the one and two stage techniques.

Who can participate?

Children aged 12-13 months who have a cleft lip and/or palate and children aged six years with no history of cleft lip and/or palate.

What does the study involve?

Participants with cleft lip and/or palate are randomly allocated to one of two groups. Those in the first group undergo the single surgical procedure to correct their deformity when they are aged 12-13 months old. Those in the second group undergo the same procedures but split over two operations, one when they are aged 12-13 months and one when they are aged 24-25 months. When children are aged three and six years old, participants in both groups have their speech and function of the soft palate assessed. In addition, a group of six year old children without cleft lip and/or palate are also recruited to assess their speech.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

GSR Institute of Craniofacial and Facial Plastic Surgery (India)

When is study starting and how long is it expected to run for?

May 2009 to April 2017

Who is funding the study?

GSR Institute of Craniofacial and Facial Plastic Surgery (India)

Who is the main contact?

Dr Rajgopal Reddy

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

ETH/CP/2009/12/008

Study information

Scientific Title

Effect of one-stage versus two-stage cleft palate repair on speech and fistula formation in children with complete unilateral cleft lip and palate: A randomised controlled trial

Study objectives

The aim of this study is to evaluate whether one or two-stage palatoplasty more effective preventing fistula formation and hypernasality in patients with complete unilateral cleft lip and palate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Independent Ethics Committee of the GSR Institute of Craniofacial and Facial Plastic Surgery, 14/12/2009, ref: ETH/CP/2009/12/008

Primary study design

Interventional

Study design

Single center parallel block randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Complete unilateral cleft palate

Interventions

Patients with non-syndromic complete unilateral cleft lip and palate with a repaired cleft lip are randomly allocated into one of two groups of 50 each using block randomisation.

Group A: Participants undergo the Bardach two-flap technique with optimal muscle dissection or levator myoplasty as a single procedure between 12-13 months. This involves cleft palate repair where the cleft of hard palate is closed using a technique called Bardach two flap technique where the mucosa over the hard palate is dissected and brought together in the midline to close the cleft palate. The cleft of soft palate is closed using a technique known as levator myoplasty. This involves the dissection of 3 of the 4 muscle groups of the soft palate, i.e. Levator veli palatine, palatoglossus and palatopharyngeus muscles, and bringing them into the midline and suturing them to the same muscle group on the other side. This muscle repositioning is covered by mucosa on the oral side as well as mucosa from the nasal side.

Group B: Participants undergo a soft palatoplasty with levator myoplasty (at 12-13 months of age) and two flap hard palatoplasty (at 24-25 months of age) as a separate procedure. This involves the same technique of repair for the hard and soft palate as detailed in the one stage procedure. The difference is that the cleft of hard palate is repaired between the age of 12 and 13 months and the cleft of soft palate is repaired between the ages of 24 and 25 months.

Participants in both groups are followed up when they are 3 and 6 years old. Follow up consists of diagnosing fistula formation at the age of 3 years and hypernasal speech at the age of 6 years.

In addition, a third group of participants aged 6 years who do not have a cleft palate are selected to act as a comparator (group C). These participants undergo speech testing to diagnose hypernasal speech at a single timepoint when they are 6 years old.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Hypernasality of speech will be measured by nasometry and perceptual outcomes at age 6 years

Key secondary outcome(s)

Fistula rates will be tested clinically using observation and non-invasive palpation at age 3 years.

Completion date

30/04/2017

Eligibility

Key inclusion criteria

Patients:

1. Patients of either gender
2. Patients aged 12-13 months
3. Non-syndromic complete unilateral cleft lip and palate with a previously repaired cleft lip

Controls:

1. Patients of either gender
2. Patients aged 6 years
3. No history of cleft lip and/or palate defect

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 Months

Upper age limit

13 Months

Sex

All

Total final enrolment

100

Key exclusion criteria

1. Bilateral cleft lip and palate
2. Isolated cleft palate
3. Patients younger than 12 months and older than 13 months of age
4. Patients with associated syndromic conditions

Date of first enrolment

01/01/2010

Date of final enrolment

27/12/2010

Locations

Countries of recruitment

India

Study participating centre

GSR Institute of Craniofacial and Facial Plastic Surgery

Vinaynagar Colony

I. S. Sadan

Saidabad

Hyderabad

India

500059

Sponsor information

Organisation

GSR Institute of Craniofacial and Facial Plastic Surgery

ROR

<https://ror.org/00pcyna40>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

GSR Institute of Craniofacial and Facial Plastic Surgery

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rajgopal R. Reddy (raj@craniofacialinstitute.org)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018	26/11/2020	Yes	No