

# 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?

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<b>Registration date</b> 31/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/11/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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

Dr Rajgopal Reddy

### ORCID ID

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### Contact details

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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

**Study design**

Single center parallel block randomised controlled trial

**Primary study design**

Interventional

**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 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](mailto:raj@craniofacialinstitute.org))

**IPD sharing plan summary**

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2018	26/11/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes