ISRCTN17288141 https://doi.org/10.1186/ISRCTN17288141

# 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

**Registration date**
31/05/2017

**Overall study status**
Completed

**Last Edited**
26/11/2020

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
http://orcid.org/0000-0001-7257-0756

### Contact details
GSR Institute of Craniofacial and Facial Plastic Surgery
Vinaynagar Colony
IS Sadan
Saidabad
Hyderabad
India
500059

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

### Secondary outcome measures
Fistula rates will tested clinically using observation and non-invasive palpation at age 3 years.

### Overall study start date
01/05/2009

### 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

### Age group
Child

### Lower age limit
12 Months

### Upper age limit
13 Months

### Sex
Both

### Target number of participants
50 participants in each experimental group and 20 in the control group

### 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

### Sponsor details

GSR Hospital
Vinaynagar Colony
IS Sadan
Saidabad
Hyderabad
India
500059
+91 984 905 9836
info@craniofacialinstitute.org

### Sponsor type
Hospital/treatment centre

### Website
www.craniofacialinstitute.org

### 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

### Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

### Intention to publish date
31/12/2018

### 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 |