

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparative evaluation of immediate and delayed addition of nasal stent to nasoalveolar molding plate on nostrils shape and cleft width among patients with unilateral cleft lip and palate

Protocol summary

Study aim

The aim of present study is to compare immediate and delayed addition of nasal stent to nasoalveolar molding plate on nostrils shape and cleft width among patients with unilateral cleft lip and palate

Design

Randomized, superiority, parallel group single blind clinical trial

Settings and conduct

Twenty infants with unilateral cleft lip and palate are included in the study. First, all patients are referred to the proficient radiology scanner for facial scans. In the control group, insertion of nasal stent into the nasoalveolar plaque is performed when the width of the cleft is 5 mm. In the intervention group, insertion of nasal stent into the nasoalveolar plaque in the initial phase of the treatment occurs when the cleft width is greater than 5 mm. The treatment continues for 2 months after insertion of the stent in each group, and ultimately the patients will be referred to the radiology clinic for a final scan of the face with the proface software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age is under one month; Alveolar width greater than 6 mm; Parent cooperation; Informed consent. Non Inclusion criteria: syndromic patient

Intervention groups

In the intervention group, insertion of nasal stent into the nasoalveolar plaque in the initial phase of the treatment occurs when the cleft width is greater than 5 mm. In the control group, insertion of nasal stent into the nasoalveolar plaque is performed when the width of the cleft width is 5 mm.

Main outcome variables

Width of the gap; columellar deviation angle; nostril width; nostril height; inter comisural distance; soft tissue cleft width; the nasal area on the left and right side of the line from Nasion to Subnasal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180828040897N1**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

Abdollah Jamalinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 8313

Email address

jamalinasaba961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of immediate and delayed addition of nasal stent to nasoalveolar molding plate on nostrils shape and cleft width among patients with unilateral cleft lip and palate

Public title

The effect of immediate and delayed addition of nasal stent to nasoalveolar molding plate among patients with unilateral cleft lip and palate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age under one month Alveolar width greater than 6 mm
Parent's cooperation Informed consent

Exclusion criteria:

Syndromic disease (patients)

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization based on blocking method

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware to what intervention or control group they will be assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Mashhad University of
Medical Sciences

Street address

Mashhad University of Medical Sciences, Vakil Abad
Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.072

Health conditions studied

1

Description of health condition studied

Cleft palate

ICD-10 code

Q35

ICD-10 code description

Cleft palate

2

Description of health condition studied

cleft lip

ICD-10 code

Q36

ICD-10 code description

Cleft lip

Primary outcomes

1

Description

columellar deviation angle: The intercalary angle that passes from the Clomarlal with the horizontal line in the subjective mental view of the radiograph

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

2

Description

nostril width: The greatest distance between the clommler and the alar of nose in each side

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

3

Description

nostril height: the distance between the anteriormost point of the nasal cavity and the posterior part of the nose

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

4

Description

inter comisural distance: the distance between the two corners of the lip

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

5

Description

soft tissue cleft width: Maximum distance from the two edges of the cleft lip

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

6

Description

The nasal area is on the left and right side of the line from Nasion to Subnasal.

Timepoint

The beginning and the end of the treatment

Method of measurement

Using proface software (picture derived from software)

7

Description

clinical width of the gap

Timepoint

Weekly until the end of the study

Method of measurement

Use a caliper with a precision of 1 mm for

8

Description

width of the gap

Timepoint

Monthly until the end of the study

Method of measurement

Based on models scanned with Cone beam computed tomography

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 10 patients with unilateral cleft of lip and palate are included. First, all patients are referred to the proficient radiology scanner for facial scans, using proface software. In this group, insertion of nasal stent into the nasopalveolar plaque is performed when the

width of the cleft is 5 mm. Each week the plaques are adjusted with selective grinding and adding of elastic materials and the gap is measured monthly. The treatment continues for 2 months after insertion of the stent in each group, and ultimately the patients will be referred to the radiology clinic for a final scan of the face with the proface software.

Category

Treatment - Devices

2

Description

Intervention group: 10 patients with unilateral cleft of lip and palate are included. First, all infants are referred to the proficient radiology scanner for facial scans, using proface software. In this group, insertion of nasal stent into the nasopalveolar plaque in the initial phase of the treatment occurs when the cleft width is greater than 5 mm. Each week the plaques are adjusted with selective grinding and adding of elastic materials and the gap is measured monthly. After 2 months of insertion of the stent, the infants will be referred to the radiology clinic for a final scan of the face with the proface software.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Ali Khakshour

Street address

Akbar Hospital. Fakori Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, in front of Daneshgah 18 avenue, Daneshgah street

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Mashhad University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 Public
Domestic or foreign origin
 Domestic
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 Academic

Person responsible for general inquiries

Contact
Name of organization / entity
 Mashhad University of Medical Sciences
Full name of responsible person
 Arezo Jahanbin
Position
 Associate professor
Latest degree
 Specialist
Other areas of specialty/work
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Person responsible for updating data

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 jamalinasaba961@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Yes - There is a plan to make this available
Study Protocol
 Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
 Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
 Yes - There is a plan to make this available
Clinical Study Report
 Yes - There is a plan to make this available
Analytic Code
 Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A portion of the data, such as data on the main outcome or like that can be shared.

When the data will become available and for how long

Starting the access period 6 months after printing results

To whom data/document is available

own data will only be available to researchers working in

academic and academic institutions

Under which criteria data/document could be used

You have to completely control the data and get the credentials from the author.

From where data/document is obtainable

Abdollah Jamalinasab. Email: abdollah.jamalinasab@yahoo.com

What processes are involved for a request to access data/document

The requestor can contact by e-mail. Information is available as soon as possible

Comments