Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of apnea, hypopnea index changes and obstructive sleep apnea correction after bone graft in alveolar cleft patients.

Protocol summary

Study aim
Determination of apnea, hypopnea index changes and obstructive sleep apnea correction after bone graft in alveolar cleft patients.

Design
This study will be performed as a double blinded quasi experimental.This is a before-after interventional pilot research which would be executed on 10 alveolar cleft patients for evaluation of apnea/hypopnea index by Apnea-link device. The person who would collect the data and also who investigate them are blind.

Settings and conduct
Oral and maxillofacial surgery department of Ghaem hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All of the patients with unilateral alveolar cleft with age range 8-15 years old who would be candidate for bone graft; BMI less than 30 kg/m2; Without congenital syndromes; Without the history of cardiovascular or respiratory diseases like rhinitis, asthma , bronchitis. Ḛxclusion criteria: Patients who would not attend for follow up; graft failure (due to exposure or infection)

Intervention groups
Intervention group: bone graft for alveolar cleft treatment group. No control group is ávailable in this study.

Main outcome variables
Apnea/hypopnea index value; postoperative obstructive sleep apnea recovery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150613022697N3**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **prospective**
Last update: **2018-06-05, 1397/03/15**
Update count: **0**

Registration date
2018-06-05, 1397/03/15

Registrant information

Name
Sahand Samiee rad

Name of organization / entity
mashhad dental school,oral and maxillofacial department

Country
Iran (Islamic Republic of)

Phone
+98 51 3883 7289

Email address
samieerads@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of apnea, hypopnea index changes and obstructive sleep apnea correction after bone graft in alveolar cleft patients.

Public title
Evaluation of obstructive sleep apnea correction after bone graft in alveolar cleft patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All of the patients with unilateral alveolar cleft with age range 8-15 years old who would be candidate for bone graft. BMI less than 30 kg/m2 ASA 1,2 Without congenital syndromes Without history of cardiovascular or respiratory diseases like rhinitis, asthma , bronchitis.

Exclusion criteria:

Graft failure (due to exposure or infection) Patients who would not attend for follow up.

Age

From **8 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Person who would be responsible for data collection and also principle investigator and analysor are blind.

Placebo

Not used

Assignment

Single

Other design features

This study will be a quasi-experimental and pilot before-after interventional research.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Mashhad university of medical sciences

Street address

Ghoreishi building, Daneshghah avenue.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.mums.sd.REC.1394.342

Health conditions studied

1

Description of health condition studied

Obstructive sleep apnea

ICD-10 code

G47.3

ICD-10 code description

Sleep apnea

2

Description of health condition studied

Alveolar cleft

ICD-10 code

Q37

ICD-10 code description

Cleft palate with cleft lip

Primary outcomes

1

Description

Apnea & Hypopnea index value.

Timepoint

1 week before surgery and 1 month postoperatively.

Method of measurement

Apnea link device measurement.

2

Description

Sleep apnea recovery.

Timepoint

1 week before surgery and 1 month postoperatively.

Method of measurement

Apnea link device measurement and questionare.

Secondary outcomes

1

Description

Sleep quality recovery.

Timepoint

1 week before surgery and 1 month postoperatively.

Method of measurement

Sleep questionnare.

Intervention groups

1

Description

Bone graft for alveolar cleft

Category

Treatment - Surgery

2

Description
No control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Sahand samiee rad
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Mashhad dental school, Vakil abad street.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Saeed Eslami
Street address
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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
50
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
Sahand Samiee rad
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Others
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oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.
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Person responsible for scientific inquiries

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Latest degree
Specialist
Other areas of specialty/work
oral and maxillofacial surgery
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Alireza Khoshsirat

Position

Chief resident

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected unindetified data would be shared for all researchers.

When the data will become available and for how long

The access to data will be started 6 months after publication.

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir

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

The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission.

Comments