

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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/m<sup>2</sup>; Without congenital syndromes; Without the history of cardiovascular or respiratory diseases like rhinitis, asthma, bronchitis. Exclusion 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 available 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

samieerad@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/m<sup>2</sup> 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 analyst 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 committee of Mashhad university of medical sciences

##### Street address

Ghoreishi building, Daneshgah 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 questionnaire.

## Secondary outcomes

### 1

#### Description

Sleep quality recovery.

#### Timepoint

1 week before surgery and 1 month postoperatively.

#### Method of measurement

Sleep questionnaire.

## 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

**Street address**

Mashhad dental school, Vakil abad street.

**City**

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**Postal code**

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**Email**

samieerads@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Saeed Eslami

**Street address**

Ghoreishi building, Daneshghah avenue.

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eslamis@mums.ac.ir

**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

**Street address**

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

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**Person responsible for scientific 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**

oral and maxillofacial surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Khoshsirafat

**Position**

Chief resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Others

**Street address**

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

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alirezakhoshsirafat85@gmail.com

## 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 unidentifiable 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 researchers (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**