

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Evaluation of clinical success of low intensity ultrasound application in comparison with conventional autogenous bone graft in the reconstruction of alveolar cleft defects in patients with clefts of hard palate and unilateral cleft of lips

#### Protocol summary

##### Study aim

Investigating the application of low intensity ultrasound in comparison with autogenous bone in the reconstruction of alveolar cleft defects

##### Design

Clinical trial with control group, with parallel groups, single blind, non-randomized, with a sample size of 14 patients

##### Settings and conduct

14 patients will be selected by using non-random sampling and from two clinics of Mashhad Dental School. Of the 14 patients, alone autologous bone graft will be done for 7 patients and others will be subjected to the pulsed ultrasound after transplantation for one minute at 1MHz frequency and 500 mW intensity for 6 weeks. In order to measure the gap size, occlusal and peri apical radiography will be used, and the two groups will be identical in this regard. Postoperative immediate CBCTs will be provided to assess the shape and appearance of graft and affected teeth. One month after surgery, patients will be examined for the progression of graft repair and growth patterns of affected teeth. At the end, the radiographic evaluation will be performed by an independent evaluator who has not participated in the preoperative orthodontic treatment for any patient in the study.

##### Participants/Inclusion and exclusion criteria

Patients with palate and lips cleft that their palatal bone has been expanded and they have been prepared for alveolar graft at age range of 9 to 13 years old and have their parent's informed consent

##### Intervention groups

In the intervention group, from day after transplantation, low-intensity ultrasound pulses will be applied for 1 minute at a frequency of 1 MHz and 500 mW in intensity for a period of 6 weeks. In the control group, the normal

procedure will be performed with the autologous bone graft of the iliac region of the patient.

##### Main outcome variables

Progression of the graft repair and the pattern of affected adjacent tooth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181022041411N1**

Registration date: **2018-12-07, 1397/09/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-07, 1397/09/16**

Update count: **0**

##### Registration date

2018-12-07, 1397/09/16

##### Registrant information

##### Name

Amirreza Mashreghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3768 3564

##### Email address

mashreghia951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

**Expected recruitment end date**

2019-09-23, 1398/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of clinical success of low intensity ultrasound application in comparison with conventional autogenous bone graft in the reconstruction of alveolar cleft defects in patients with clefts of hard palate and unilateral cleft of lips

**Public title**

Evaluation of success of low intensity ultrasound application in the reconstruction of alveolar bone

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with unilateral palate and lips cleft Patients who their palatal bone has been expanded Parental informed consent

**Exclusion criteria:**

Patients with bilateral palate and lips clefts Patients with other syndromes Patients who can not be surgically treated because of medical problems

**Age**

From **9 years** old to **13 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **14**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The analyst will be unaware of the intervention and control groups because the data will be presented as anonymous code to the statistician.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Faculty of Dentistry-Mashhad University of Medical Sciences

**Street address**

Mashhad dental school, Vakilabad Boulevard

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Approval date**

2018-05-16, 1397/02/26

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1397.012

**Health conditions studied****1****Description of health condition studied**

Cleft hard palate with unilateral cleft lip

**ICD-10 code**

Q37.1

**ICD-10 code description**

Cleft hard palate with unilateral cleft lip

**Primary outcomes****1****Description**

The progression of the graft repair and the pattern of affected adjacent tooth

**Timepoint**

1, 3 and 6 months after bone graft surgery

**Method of measurement**

Radiographic images of CBCT, occlusal and periapical

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: From the day after the transplantation, patients will be subjected to pulsed ultrasound at low intensity for 1 minute at a frequency of 1 MHz and an intensity of 500 mW for 6 weeks.

**Category**

Treatment - Other

## 2

### Description

Control group: The normal procedure will be performed with the autologous bone graft of the iliac region of the patient

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of palatal and lip cleft of Mashhad dental school

##### Full name of responsible person

Dr. Arezoo Jahanbin

##### Street address

Mashhad dental school, Vakilabad boulevard

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9501

##### Email

mail@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Arezoo Jahanbin

##### Street address

Mashhad dental school, Vakilabad boulevard

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9501

##### Email

mail@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

30

##### 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

### 2

#### Sponsor

##### Name of organization / entity

Deputy of Research of Mashhad University of Medical Sciences

##### Full name of responsible person

Hossein Bagheri

##### Street address

Mashhad dental school, Vakilabad boulevard.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

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##### Phone

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##### Email

mail@mums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

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Deputy of Research of Mashhad University of Medical Sciences

##### Proportion provided by this source

30

##### 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

Amirreza Mashreghi

##### Position

Assistant of orthodontics

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

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**Email**

mashreghia891@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Arezoo Jahanbin

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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jahanbina@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Amirreza Mashreghi

**Position**

Resident of orthodontics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable