

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)

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+98 51 3768 3564

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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 illiac 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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

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Grant name

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

Mashhad University of Medical Sciences

Full name of responsible person

Arezoo Jahanbin

Position

Professor

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Resident of orthodontics

Latest degree

Medical doctor

Other areas of specialty/work

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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