

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

A randomized clinical trial on effectiveness of Plasma Rich in Growth Factors (PRGF) in combination with iliac autogenous bone graft versus PRGF with Demineralized Bone Matrix (DBM) in repairing of alveolar clefts

Protocol summary

Summary

The standard method for alveolar cleft treatment is bone grafting from iliac bone. However, osseointegration may not occur in some. Efforts have been made to improve the surgery results by using several plasma factors such as PRP, PRGF, BMP-2, etc. There are also studies reporting successful results using allografts with or without growth factors. The main objective of this study is to compare the application of autogenous iliac bone grafting with PRGF versus DBM with PRGF in unilateral cleft bone treatment. The study population included unilateral lip and palate and alveolar cleft patients. They were categorized into secondary and tertiary graft groups according to their dental development. The patients in the secondary or tertiary graft categories were randomly assigned into the two intervention groups: grafting with iliac +PRGF (n=16) and grafting with DBM+PRGF (n=16). The outcome will be measured six months later as the proportion of the remaining bone to the pre-surgery cleft volume.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801161790N1**

Registration date: **2010-12-04, 1389/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-04, 1389/09/13

Registrant information

Name

Gholamreza Shirani

Name of organization / entity

Dentistry, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research center, dental school, Tehran university of medical sciences

Expected recruitment start date

2008-05-04, 1387/02/15

Expected recruitment end date

2009-09-21, 1388/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial on effectiveness of Plasma Rich in Growth Factors (PRGF) in combination with iliac autogenous bone graft versus PRGF with Demineralized Bone Matrix (DBM) in repairing of alveolar clefts

Public title

A randomized clinical trial on effectiveness of Plasma Rich in Growth Factors (PRGF) in combination with iliac autogenous bone graft versus PRGF with Demineralized Bone Matrix (DBM) in repairing of alveolar clefts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Presence of unilateral alveolar cleft in lip and palate cleft patients, 2) The age range of 8 to 30 years, Exclusion criteria: 1) Systemic disease or congenital syndrome 2) Patients who have previously had the same operation

Age

From **8 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences

Street address

Ghods St., crossing with Keshavarz St.,

City

Tehran

Postal code

Approval date

2009-08-04, 1388/05/13

Ethics committee reference number

88-02-69-7155

Health conditions studied

1

Description of health condition studied

Repair of alveolar cleft in lip and palatal cleft patients

ICD-10 code

Q37.5

ICD-10 code description

Cleft hard and soft palate with unilateral cleft lip

Primary outcomes

1

Description

Formation of bony bridge in alveolar cleft

Timepoint

6 month

Method of measurement

Measuring of bony bridge volume in alveolar cleft in ct scan

Secondary outcomes

1

Description

Determining volume of bone formation

Timepoint

6 month

Method of measurement

measuring of volume of grafted bone by ct scan

Intervention groups

1

Description

Application of DBM in combination with PRGF in Alveolar cleft grafting (Intervention group)

Category

Treatment - Other

2

Description

Application of autogenous Iliac crest bone in combination with PRGF in Alveolar cleft grafting (control group)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Maxillofacial Surgery Clinic of Shariati Hospital

Full name of responsible person

Dr Amir Jalal Abbasi

Street address

Maxillofacial Surgery Clinic of Shariati Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Elaheh Alamdar

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Ghods St., crossing with Keshavarz St.,

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Grant name**Grant code / Reference number**

88-02-69-7155

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

Yes

Title of funding source

Vice chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Dental Faculty of Tehran University of Medical Sciences

Full name of responsible person

Dr Amir Jalal Abbasi

Position

Resident of maxillofacial surgery

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty