Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Treatment results of combined platelet-riched plasma and fat injection in patients with velopharyngeal insufficiency referral to Imam Khomeini Hospital between 2012-2013 years

Protocol summary

Summary

Objectives: This study is aimed to evaluate treatment results of combined platelet-riched plasma and fat injection in patients with velopharyngeal insufficiency referral to Imam Khomeini Hospital between 2012-2013 years Design: Prospective clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Patients with velopharyngeal insufficiency admitted in plastic surgery ward in Imam Khomeini Hospital between 2012-2013 years, were included. Intervention: Combined injection of platelet-rich plasma (1 ml) and fat (4 ml) at the medial site of obstruction during velopharyngeal words are pronounced. Platelet-rich plasma was prepared from 10 ml of venous blood and fat of the abdomen was taken. Main outcome measures (variables): Gap velopharyngeal ; Lateral displacement of the soft palate and the posterior pharyngeal wall motion analysis of video naso endoscopy; hypernasal resonance; Nasal air escape; Intelligibility.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306018435N5**
Registration date: **2013-06-10, 1392/03/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-10, 1392/03/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-08-10, 1391/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment results of combined platelet-riched plasma and fat injection in patients with velopharyngeal insufficiency referral to Imam Khomeini Hospital between 2012-2013 years

Public title

Treatment results of combined platelet-rich plasma and fat injection in patients with velopharyngeal insufficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with repaired cleft palate; Patients aged 15-20 years;Patients with any defects in

the pharyngeal wall area and volume;Patients undergoing injection of combined platelet-rich plasma and fat; Patients with mild to moderate velopharyngeal insufficiency confirmed by nasoendoscopy; signing consent to participate in the study. Exclusion criteria: Neurological impairment ; Mental retardation; Tumor area velopharyngeal; Hearing loss; Presence of pharyngeal flap; Oronasal fistula;Large tonsils; Severe velopharyngeal insufficiency.

Age
From **15 years** old to **20 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences and Health Services

Street address
Poorsina Ave.

City
Tehran

Postal code

Approval date
2013-06-01, 1392/03/11

Ethics committee reference number
92/D/130/396

Health conditions studied

1

Description of health condition studied
Velopharyngeal insufficiency

ICD-10 code
M70.9

ICD-10 code description
Unspecified soft tissue disorder related to use, overuse and pressure

Primary outcomes

1

Description
Gap velopharyngeal

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Nasal endoscopy video analysis

2

Description
Displacement of the soft palate

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Nasal endoscopy video analysis

3

Description
Lateral and the posterior pharyngeal wall motion

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Nasal endoscopy video analysis

4

Description
Hypernasal resonance

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Repeat the words and phrases

5

Description
Nasal air escape

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Repeat the words and phrases

6

Description
Intelligibility

Timepoint
Before the injection, at 6 weeks and 6 months after the injection

Method of measurement
Repeat the words and phrases

Secondary outcomes

empty

Intervention groups

1

Description
combined platelet-rich plasma and fat injection
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Hamid Reza Fathi
Street address
Gharib St., Keshavarz Blvd.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Shahin Akhunzadeh MD.
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Poursina St.
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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
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
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
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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