

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

##### Name

Seyed Masoud Hashemi

##### Name of organization / entity

Department of Anesthesiology and Pain

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2261 2252

##### Email address

mohammadinasab@alumnus.tums.ac.ir

##### 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**

Tehran

**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.

**Street address**

Poursina St.

**City**

Tehran

**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**

Imam Khomeini Hospital

**Full name of responsible person**

Hamid Reza Fathi

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Gharib St., Keshavarz Blvd.

**City**

Tehran

**Postal code****Phone**

+98 21 6643 8153

**Fax****Email**

hamifathi@yahoo.com

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

Imam Khomeini Hospital

**Full name of responsible person**

Hamid Reza Fathi

**Position**

Plastic and Reconstructive Surgeon

**Other areas of specialty/work****Street address**

Gharib St., Keshavarz Blvd.

**City**

Tehran

**Postal code****Phone**

+98 21 6643 8153

**Fax****Email**

hamifathi@yahoo.com

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

Imam Khomeini Hospital

**Full name of responsible person**

Hamid Reza Fathi

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Gharib St., Keshavarz Blvd.

**City**

Tehran

**Postal code**

**Phone**

+98 21 6643 8153

**Fax****Email**

hamifathi@yahoo.com

**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*