

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the Effectiveness of Teriparatide and Placebo in Enhancing Rotator Cuff Tendon Healing in Patients after Rotator Cuff Arthroscopic Repair Surgery

#### Protocol summary

##### Study aim

Determining the effect of Teriparatide on healing after arthroscopic rotator cuff repair surgery

##### Design

A clinical trial with the control group, with parallel groups, triple-blind, randomized, on 70 patients. The blocking method is used for randomization.

##### Settings and conduct

This study will be performed at Imam Khomeini Complex Hospital of Tehran. A randomized, triple-blind, control clinical trial is carried out on 70 patients. The surgeon, assessor, data statistician, and patient are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of rotator cuff rupture clinically and with MRI findings and patient informed consent obtain. Exclusion criteria: refusal to participate in the study; previous shoulder surgery; history of shoulder septic arthritis; patients with combined shoulder surgeries than rotator cuff repair; non-operable rotator cuff tear; contraindication in using Recombinant Human Parathyroid Hormone (rhPTH); patients under radiation therapy; known case of any psychological disorders; pregnancy; hypo/hyper Calcemia/Calciuria.

##### Intervention groups

Group 1: Daily use of 20 µg of rhPTH drug subcutaneously for 3 months. Group 2: placebo consumption for three months including mannitol, sodium acetate anhydrous wfi, 10% Glacial acetic acid, meta-cresol, Hydrochloric acid solution 10%, sodium hydroxide solution

##### Main outcome variables

Shoulder Range of Motion; Shoulder Pain Visual Analogue Score; Rotator Cuff Healing by MRI evaluation via Sugaya score; Shoulder Function via ASES Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220809055649N1**

Registration date: **2023-06-01, 1402/03/11**

Registration timing: **retrospective**

Last update: **2023-06-01, 1402/03/11**

Update count: **0**

##### Registration date

2023-06-01, 1402/03/11

##### Registrant information

##### Name

Amir Human Hoveidaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 0227

##### Email address

ah-hoveidaei@farabi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-21, 1400/01/01

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

2021-03-21, 1400/01/01

##### Actual recruitment end date

2023-03-21, 1402/01/01

##### Trial completion date

2023-03-21, 1402/01/01

## Scientific title

Comparison of the Effectiveness of Teriparatide and Placebo in Enhancing Rotator Cuff Tendon Healing in Patients after Rotator Cuff Arthroscopic Repair Surgery

## Public title

Teriparatide in Post-op Rotator Cuff Healing

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosis of rotator cuff rupture clinically and with MRI findings. Patient Informed Consent is obtained

### Exclusion criteria:

Refusal to participate in the study  
Previous shoulder surgery  
History of shoulder septic arthritis  
Patients with combined shoulder surgeries than rotator cuff repair  
Non-operable rotator cuff tear  
Contraindication in using Recombinant Human Parathyroid Hormone (rhPTH)  
Patients under radiation therapy  
Known case of any psychological disorders  
Pregnancy  
Hypo/Hyper Calcemia/Calciuria

## Age

From **50 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **50**

Actual sample size reached: **43**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocks of 4 are used for randomization, considering that data will be collected from two wards of Imam Khomeini Complex Hospital of Tehran are selected in the stratification factors section. For blinding, the drug manufacturing company will be asked to make a placebo, in this way, the surgeon will be provided with drugs completely similar to the original drug with blinded codes (by the pharmaceutical company) to use for the patients, randomly. Patients are also informed that they may be in the treatment or control group. At the end of the study, the statistician, having the list of blinded codes of the pharmaceutical company, will only be informed which codes are in the same group (treatment or control).

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The surgeon will be provided with drugs completely similar to the original drug with blinded codes (by the pharmaceutical company) to use for the patients,

randomly. Patients are also informed that they may be in the treatment or control group. At the end of the study, the statistician, having the list of blinded codes of the pharmaceutical company, will only be informed which codes are in the same group (treatment or control).

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Imam Khomeini Hospital Complex - Tehran University of Medical Sciences

##### Street address

Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

#### Approval date

2021-01-27, 1399/11/08

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1399.493

## Health conditions studied

### 1

#### Description of health condition studied

Arthroscopic rotator cuff repair

#### ICD-10 code

S46.0

#### ICD-10 code description

Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

## Primary outcomes

### 1

#### Description

Shoulder Range of Motion (Active/Passive Flexion and External Rotation)

#### Timepoint

6 months and 1 year

#### Method of measurement

Physical examination based on degrees

## 2

### **Description**

Post-operative pain score

### **Timepoint**

6 months and 1 year

### **Method of measurement**

Visual Analogue Scale

## 3

### **Description**

Rotator Cuff Healing

### **Timepoint**

1 year

### **Method of measurement**

By MRI evaluation via Sugaya score

## 4

### **Description**

Shoulder Function

### **Timepoint**

pre-op and 1 year post-op

### **Method of measurement**

ASES Score

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Daily use of 20 µg of rhPTH drug subcutaneously for 3 months

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: placebo consumption for three months including mannitol, sodium acetate (anhydrous wfi, 10% Glacial acetic acid, meta-cresol, Hydrochloric acid solution 10%, sodium hydroxide solution

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

##### **Full name of responsible person**

Mohammadreza Guity

##### **Street address**

Imam Khomeini Hospital Complex, Tohid Square,

Tehran, Iran

##### **City**

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##### **Province**

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##### **Postal code**

1419733141

##### **Phone**

+98 21 6119 0000

##### **Email**

imamhospital@tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Akbar Fotuhi

##### **Street address**

Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

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afotouhi@tums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran University of Medical Sciences

#### **Proportion provided by this source**

100

#### **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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Amir Human Hoveidaei

##### **Position**

Senior Research Fellow

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Sports Medicine Research Center, No.7, Al-e Ahmad Highway, Tehran

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

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**Full name of responsible person**

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**Position**

Associate professor

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

Tehran University of Medical Sciences

**Full name of responsible person**

Shahabaldin Beheshti Fard

**Position**

Orthopedic Surgery Resident

**Latest degree**

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**Other areas of specialty/work**

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**Fax****Email**

shahab.dr71@gmail.com

**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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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