Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 anhydous 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 therpay 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 Squre, 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 (anhydous 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 Squre, Tehran, Iran
City
Tehran
Province
Tehran
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 Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
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
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 8863 0227
Fax
Email
hoveidaei.a.h@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Guity
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Fax
Email
m_guity@yahoo.com

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
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
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