

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the results of anteromedial and anterolateral tibial tunnel methods in posterior cruciate ligament reconstruction: a randomized clinical trial

#### Protocol summary

##### Study aim

To compare the results of anteromedial and anterolateral tibial tunnel methods in posterior cruciate ligament reconstruction

##### Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention groups

##### Settings and conduct

This study will be performed in the Besat Hospital in Hamadan city on 36 eligible patients. The patients will be randomly assigned to the intervention groups through the block randomization. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years Rupture of the posterior cruciate tendon Exclusion criteria: Coagulopathy disorder

##### Intervention groups

Intervention group 1: Arthroscopic surgery of the knee in order to reconstruct the posterior cruciate ligament of the knee by using single-strand Achilles graft through the medial anterior tibial tunnel while the knee is in 90 degree flexion. Intervention group 2: Arthroscopic surgery of the knee in order to reconstruct the posterior cruciate ligament of the knee by using single-strand Achilles graft through the medial lateral tibial tunnel while the knee is in 90 degree flexion.

##### Main outcome variables

Primary outcome: Average pain score, the average time to return to daily activities, the average range of motion limitation Secondary outcome: Hematoma

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120215009014N472**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

#### Registration date

2023-05-03, 1402/02/13

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-05-22, 1402/03/01

#### Expected recruitment end date

2023-06-22, 1402/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the results of anteromedial and anterolateral tibial tunnel methods in posterior cruciate ligament reconstruction: a randomized clinical trial

#### Public title

Comparison of the results of anteromedial and anterolateral tibial tunnel methods in posterior cruciate ligament reconstruction

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age of 18 to 65 years Rupture of the posterior cruciate tendon

##### Exclusion criteria:

Coagulopathy disorder

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **36**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2023-04-29, 1402/02/09

#### Ethics committee reference number

IR.UMSHA.REC.1402.040

## Health conditions studied

### 1

#### Description of health condition studied

Rupture of the posterior cruciate tendon

#### ICD-10 code

M23.62

#### ICD-10 code description

Other spontaneous disruption of posterior cruciate ligament of knee

## Primary outcomes

### 1

#### Description

Average pain score

#### Timepoint

In the fourth and eighth weeks and the third month after surgery

#### Method of measurement

Using a visual analog scale (VAS)

### 2

#### Description

The average time to return to daily activities

#### Timepoint

In the fourth and eighth weeks and the third month after surgery

#### Method of measurement

By taking a history

### 3

#### Description

The average range of motion limitation

#### Timepoint

In the fourth and eighth weeks and the third month after surgery

#### Method of measurement

Using the Lysholm Knee Scoring Scale

## Secondary outcomes

### 1

#### Description

Hematoma

#### **Timepoint**

In the fourth and eighth weeks and the third month after surgery

#### **Method of measurement**

With clinical examination

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: Arthroscopic surgery of the knee in order to reconstruct the posterior cruciate ligament of the knee by using single-strand Achilles graft through the medial anterior tibial tunnel while the knee is in 90 degree flexion.

##### **Category**

Treatment - Surgery

#### **2**

##### **Description**

Intervention group 2: Arthroscopic surgery of the knee in order to reconstruct the posterior cruciate ligament of the knee by using single-strand Achilles graft through the medial lateral tibial tunnel while the knee is in 90 degree flexion.

##### **Category**

Treatment - Surgery

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Besat Hospital in Hamadan city

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

Dr Alireza Naderi

###### **Street address**

Besat Hospital, Shahed Square

###### **City**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838695

###### **Phone**

+98 81 3364 0030

###### **Email**

alirezanader97@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

Hamedan University of Medical Sciences

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

Dr. Reza Shokoohi

##### **Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### **City**

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##### **Province**

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##### **Postal code**

Hamadan University o

##### **Phone**

+98 81 3838 0717

##### **Email**

info.research@umsha.ac.ir

##### **Grant name**

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

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

Yes

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

Hamedan 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**

Hamedan University of Medical Sciences

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

Dr Alireza Naderi

###### **Position**

Resident of Orthopedic

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

Orthopedics

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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### **Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Ghorbani Amjad

**Position**

Orthopedist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

### **Other areas of specialty/work**

Epidemiology

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### **Postal code**

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### **Phone**

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### **Email**

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## **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