

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of iliotibial band tightness and its release on postoperative pain after total knee arthroplasty in patients with varusgonarthrosis

#### Protocol summary

##### Study aim

The effect of iliotibial band tightness and its release on postoperative pain after total knee arthroplasty in patients with varusgonarthrosis

##### Design

The study will be double blind and clinical trial. 114 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3

##### Settings and conduct

Patients Candidate for knee arthroplasty surgery in Valiasr Hospital in Arak are divided into 3 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 years and up, patients with osteoarthritis and varus of the knee referred for knee arthroplasty, absence of underlying disease, absence of mental illness

##### Intervention groups

Patients will be evaluated for stiffness at the end of the operation. If they do not have iliotibial band stiffness, they will be placed in the control group. Cases with iliotibial band stiffness will be randomly divided into two groups. The first group of intervention that iliotibial band will be released and the second group of intervention that iliotibial band will not be released.

##### Main outcome variables

Pain, joint stability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211207053320N1**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

##### Registration date

2022-01-27, 1400/11/07

##### Registrant information

###### Name

Mohammad Zarei dejkoo

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3223 1103

###### Email address

mohammadzareei22@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-10, 1400/10/20

##### Expected recruitment end date

2023-01-10, 1401/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of iliotibial band tightness and its release on postoperative pain after total knee arthroplasty in patients with varusgonarthrosis

##### Public title

The effect of iliotibial band tightness and its release on postoperative pain after total knee arthroplasty in patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

40 years and up Patients with osteoarthritis and varus of the knee referred for knee arthroplasty Absence of underlying disease Absence of mental illness

**Exclusion criteria:**

Lack of conscious consent Death

**Age**

From 40 years old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 114

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 3 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double-blind. The analysis is done by the analyst and outcome evaluator (two-blind) and the participant. Analysts, evaluators and participants are not aware of the consequences of grouping. Surgery is performed by an assistant of orthopedist. Patients are followed up and variables are reviewed by the project resident

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

**Street address**

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2021-11-17, 1400/08/26

**Ethics committee reference number**

IR.ARAKMU.REC.1400.232

**Health conditions studied****1****Description of health condition studied**

Knee arthroplasty

**ICD-10 code**

T84.9

**ICD-10 code description**

Unspecified complication of internal orthopaedic prosthetic device, implant and graft

**Primary outcomes****1****Description**

Pain

**Timepoint**

2 weeks and one month and three months and 6 months and one year later

**Method of measurement**

Visual analog pain questionnaire

**2****Description**

Joint stability

**Timepoint**

2 weeks and one month and three months and 6 months and one year later

**Method of measurement**

International Knee Documentation Committee (IKDC)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: If they do not have iliotibial band stiffness, they will be included in the control group. Routine surgery will be performed.

**Category**

Treatment - Surgery

**2****Description**

Intervention group: Patients are evaluated for stiffness at

the end of the operation. The first group of intervention that iliotibial band will be released duration surgery. All peripheral femoral tibia osteophytes should be removed before any soft tissue is released. In tibia, release can be done with osteotomy priority. In femoral part, it is done by sharp dissection.

#### Category

Treatment - Surgery

### 3

#### Description

Intervention group: Patients will be evaluated for stiffness at the end of the operation. second group of intervention that iliotibial band will not be released duration surgery.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital

##### Full name of responsible person

Dr Hosseinali Hadi

##### Street address

Valiasr hospital, Valiasr squire

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3222 2003

##### Email

hadi@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Alireza Kamali

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3222 2003

##### Email

alikalaliir@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammadreza Bozorgmanesh

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

bozorgmanesh@arakmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Hosseinali Hadi

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

hadi@arakmu.ac.ir

**Postal code**

3814957558

**Phone**

+98 86 3223 1103

**Fax****Email**

mohammadzareii22@yahoo.com

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

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Zarei dejkooch

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**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