Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim
The effect of iliotibial band tightness and its release on postoperative pain after total knee arthrplasty 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 dejkooh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3223 1103

Email address
mohammadzarei22@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 arthrplasty in patients with varusgonarthrosis

Public title
The effect of iliotibial band tightness and its release on postoperative pain after total knee arthrplasty 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 Comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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 squre

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

alikamaliir@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 squre, 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 squre, Shahid Shirodi street

City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
hadi@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Zarei dejkooh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3223 1103
Fax
Email
mohammadzarei22@yahoo.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