

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Outcome evaluation of total knee arthroplasty among patients with and without previous high tibial osteotomy

Protocol summary

Summary

In this study, we evaluated the clinical outcomes of total knee arthroplasty after proximal tibial osteotomy as the case group and primary total knee arthroplasty as the control group in the patients with medial compartment osteoarthritis of the knee in Rasule-Akram hospital. The control group was constructed to be matched in terms of age, gender, and etiology with the case group. 38 patients (41 knees) went under total knee arthroplasty due to unsuccessful proximal tibial osteotomy as the case group and 42 patients (43 knees) underwent the primary total knee arthroplasty as the control group. This study was carried out during 2004 and 2008 on the patients above 18 years old and without a history of previous knee arthroplasty, who were suffering from severe pain or progressive osteoarthritis which made them candidates to total knee arthroplastic surgery. All the patients were followed for at least 2 years. The evaluation was performed using Hospital for Special Surgery Rating Scale (HSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902053011N1**

Registration date: **2010-05-22, 1389/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-22, 1389/03/01

Registrant information

Name

Ehsan Akbarian

Name of organization / entity

Department of Public Health Sciences, Karolinska Institutet

Country

Sweden

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Recruitment status

Recruitment complete

Funding source

Rasoule Akram Hospital

Expected recruitment start date

2003-03-20, 1381/12/29

Expected recruitment end date

2006-03-20, 1384/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcome evaluation of total knee arthroplasty among patients with and without previous high tibial osteotomy

Public title

Outcome evaluation of total knee arthroplasty among patients with and without previous high tibial osteotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: indication of performing total knee arthroplasty Exclusion criteria: ages of below 18; history of previous total knee arthroplasty

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Research Committee of Rasoul-e-Akram Hospital

Street address

Sattarkhan Ave.

City

Tehran

Postal code

Approval date

2010-05-01, 1389/02/11

Ethics committee reference number

20826

Health conditions studied

1

Description of health condition studied

Knee arthrosis

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

Primary outcomes

1

Description

(HSS rating scale (hospital for special surgery

Timepoint

1 month post-op, 3 months after that and then every 6 months until 2 years postop

Method of measurement

HSS is evaluated according to pain, function, motion, muscular strength, flexion deformity, and instability.

Secondary outcomes

empty

Intervention groups

1

Description

total knee arthroplasty after osteotomy

Category

Treatment - Surgery

2

Description

primaty total knee arthroplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram General Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasoule Akram Hospital, Orthopedics ward

Full name of responsible person

Dr Hossein Farahini

Street address

Niayesh st., Sattar khan Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasoule Akram Hospital, Orthopedics ward

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Karolinska Institutet

Full name of responsible person

Ehsan Akbarian, MD

Position

Researcher

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Name of organization / entity

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Full name of responsible person

Dr Hossein Farahini

Position

Associate Prof of Orthopedics

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty