

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of walking gait following mechanical and kinematic alignment in total knee arthroplasty

Protocol summary

Study aim

comparison of walking gait following mechanical and kinematic alignment in total knee arthroplasty

Design

Thirty patients with osteoarthritis of the knee who are candidates for knee replacement surgery and are referred to Imam Hossein Hospital are randomly divided into two groups of 15 patients, one with mechanical alignment surgery and the other with kinematic alignment surgery. After surgery, gait analysis is performed for each group and the surgical results of the two groups are compared with gait analysis.

Settings and conduct

Patients with osteoarthritis of the knee who are candidates for knee replacement surgery and are referred to Imam Hossein Hospital are divided into two groups, for one group surgery with mechanical alignment and for the other surgery with kinematic alignment. Before and after surgery for Each group has a gait analysis and the surgical results of the two groups are compared

Participants/Inclusion and exclusion criteria

Patients with knee DJD are candidates for knee replacement who have no other problems with normal gait

Intervention groups

Patients with osteoarthritis of the knee who are candidates for knee replacement surgery are divided into two groups: for one group surgery with mechanical alignment and for the other surgery with kinematic alignment

Main outcome variables

Finding a better surgical method for clinical improvement and greater patient satisfaction after total knee arthroplasty surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049171N1**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-22, 1399/09/02**

Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

ahmad nazarimoghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

dashtodarya@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of walking gait following mechanical and kinematic alignment in total knee arthroplasty

Public title

مقایسه تأثیر دو روش جراحی الاینمنت مکانیکال و الاینمنت کینماتیک
TKA در پارامترهای gait نرمال

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with knee osteoarthritis who are candidates for total knee arthroplasty surgery

Exclusion criteria:

Patients who had other lower limb surgery that prevents normal gait

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who refer to Imam Hossein Hospital with evidence of knee DJD for total knee arthroplasty are admitted to the study randomly for surgery with two methods of mechanical alignment and kinematic alignment. In this study, a simple randomization method is used and the randomization tool is a table of random numbers.

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**

Shahid Beheshti University of Medical Sciences

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valenjac

City

tehran

Province

Tehran

Postal code

0123456789

Approval date

2020-10-28, 1399/08/07

Ethics committee reference number

IR.SBMU.MSP.REC.1399.383

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

Knee osteoarthritis and knee replacement

ICD-10 code

M00-M99

ICD-10 code description

diseases of the musculoskeletal system and connective tissue

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

gait analysis

Timepoint

Before and after surgery

Method of measurement

Motion analysis device

Secondary outcomes**1****Description**

Three-dimensional movement of the knee joint

Timepoint

Before and after surgery

Method of measurement

Motion analysis device

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

Intervention group 1: In the first intervention group, knee replacement surgery will be performed as a kinematic alignment.

Category

Treatment - Surgery

2**Description**

Intervention group 2: In the first intervention group, knee replacement surgery will be performed as a mechanical alignment.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

emam hossin hospital

Full name of responsible person

ahmad nazari

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

mohamadi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

ahmad nazari

Position

medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

From the year 2022

To whom data/document is available

Our data will only be available to researchers working in academia and academia

Under which criteria data/document could be used

To write scientific research and articles

From where data/document is obtainable

ahmad nazari tehran iran 00989188571563

dashtodarya@gmail.com

What processes are involved for a request to access data/document

Contact the researcher and obtain a license from Shahid Beheshti University of Medical Sciences

Comments