Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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+98 21 7343 0000

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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 تاثیر دو روش جراحی الاینمنت مکانیکال و الاینمنت کینماتیک نرمال gait در پارامترهای TKA
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
Street address
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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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
Orthopedics

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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