Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Safety assessment of I-Tech Prostheses (Iranian Company) in Patients with Knee Osteoarthritis Following Total Knee Arthroplasty, at Shafa Yahyaian Hospital: A Phase-1 Clinical Trial

Protocol summary

Study aim
Safety assessment of I-Tech Prostheses in Patients with Knee Osteoarthritis

Design
phase one clinical trial without control group on 15 patients

Settings and conduct
In this Phase-1 Clinical Trial, 15 patients with osteoarthritis who are candidates for total knee replacement surgery at Shafa Yahyaian Hospital will be enrolled in the study. Thus, 15 patients with osteoarthritis of the knee who are on the knee replacement surgery list will be enrolled in the study after the clinical plan is explained by colleagues and informed consent is obtained, and they will be followed up for 12 months.

Participants/Inclusion and exclusion criteria
Patients with knee osteoarthritis grade 3 or 4 K-L, both genders, age between 45-65 years.

Intervention groups
Patients with knee osteoarthritis grade 3 or 4 K-L who underwent TKA with I-Tech prosthesis Iranian company

Main outcome variables
Patients will be followed for 12 months for infection, range of motion, pain, function, and quality of life. Follow-ups will be based on clinical assessment of pain reduction (KSS: Knee society score, VAS: Visual analog scale, WOMAC: Western Ontario and McMaster Universities Osteoarthritis Score, Kujala Anterior Knee Pain Scale), overall joint function, patient walking distance, and imaging findings (X-ray) at specific times (4 weeks, 3 months, 6 months, and 12 months after surgery).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260523069503N1**
Registration date: **2026-06-16, 1405/03/26**
Registration timing: **prospective**

Last update: **2026-06-16, 1405/03/26**
Update count: **0**

Registration date
2026-06-16, 1405/03/26

Registrant information

Name
Mohammad Hassanzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3354 2005

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hassanzadeh.moh@iums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety assessment of I-Tech Prostheses (Iranian

Company) in Patients with Knee Osteoarthritis Following Total Knee Arthroplasty, at Shafa Yahyaian Hospital: A Phase-1 Clinical Trial

Public title
Safety assessment of I-Tech Prostheses (Iranian Company) in Patients with Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age between 45-65 years Knee osteoarthritis grade 3 or 4 Kellgren Lawrence (diagnosis based on standing knee X-Ray) knee joint malalignment less than 30 degrees (based on 3-joint view radiograph) Visual analog scale equal or more than 5 Written informed consent
Exclusion criteria:
BMI > 35 Coagulopathic diseases or use of anticoagulant medications Proven immune system defect History of cancer or active cancer Uncontrolled underlying diseases [including: diabetes (HbA1c >8.5)] or organ failure [including: liver (ALT, AST >100 U/L), kidney (Cr>2), heart (EF<45%)] Need for corticosteroids Positive viral tests (including: HIV Ab+/HBSAg/ HTLV1,2 Ab+/ HCV Ab+/ VDRL+) Participating in another clinical trial at the same time Severe inflammation of the knee joint as a result of infection (septic arthritis) or a history of knee joint infection Substance abuse Lack of sufficient cooperation in carrying out the plan and necessary follow-up
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Shafa Yahyaian Hospital, next to the Islamic Counci, Mujahideen Islam Street, Baharestan Sq,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1157637131
Approval date
2026-04-28, 1405/02/08
Ethics committee reference number
IR.IUMS.REC.1405.036

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
pain after TKA
Timepoint
4 weeks, 3, 6 and 12 months after surgery
Method of measurement
Using VAS questionnare

Secondary outcomes

1

Description
quality of life after TKA
Timepoint
3, 6 and 12 months after surgery
Method of measurement
(KSS:Knee society score - WOMAC:Western Ontario and McMaster Universities Osteoarthritis Score,- Kujala Anterior Knee Pain Scale

Intervention groups

1

Description
Intervention group: Patients with knee osteoarthritis grade 3 or 4 K-L who underwent TKA with I-Tech prosthesis Iranian company
Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Yahyaian Hospital

Full name of responsible person
Abolfazl Bagherifard

Street address
Shafa yahyaeian hospital, next to the Islamic Council, Mujahideen Islam Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
I-Tech Company

Full name of responsible person
Nasr Eradati

Street address
No. 1, Taleghani (Hafez) Alley, Between Qanat and Dibaji Crossroads, Dolat Street, Shariati Street, Tehran

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3164115812

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+98 912 218 8190

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nasr.eradati@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
I-Tech Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Hassanzadeh

Position
Knee Fellowship

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Shafa Yahyaeian hospital, next to the Islamic Council, Mujahideen Islam Street, Tehran

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Abolfazl Bagherifard

Position
Professor

Latest degree
Subspecialist

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Knee Fellowship

Latest degree
Specialist

Other areas of specialty/work
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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
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All the necessary information will be published in the article extracted from this study, and more information can be obtained through correspondence and requests from the responsible author.

When the data will become available and for how long
Access period begins after results are Published.

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The use of data for scientific and research activities will be permitted in consultation with the corresponding author.

From where data/document is obtainable
Dr. Abolfazl Bagherifard - Shafa Yahyaian Hospital - Tehran, Shohada Square, Mojahedin Islam Street, not far from the Parliament building, opposite the gas station, Shafa Yahyaian Hospital - Postal Code: 1157637131 - Phone: 021 3354 2001-bagherifd@gmail.com

What processes are involved for a request to access data/document
Official email request to the corresponding author stating the reasons for the request from an academic email - after review within one to two business weeks

Comments