

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 3354 2005

Email address

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		Ethics committee of Iran University of Medical Sciences	
Public title		Street address	
Safety assessment of I-Tech Prostheses (Iranian Company) in Patients with Knee Osteoarthritis		Shafa Yahyaian Hospital, next to the Islamic Council, Mujahideen Islam Street, Baharestan Sq,Tehran, Iran	
Purpose		City	
Treatment		Tehran	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Tehran	
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		Postal code	
Exclusion criteria:		1157637131	
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		Approval date	
Age		2026-04-28, 1405/02/08	
From 45 years old to 65 years old		Ethics committee reference number	
Gender		IR.IUMS.REC.1405.036	
Both		Health conditions studied	
Phase		1	
1		Description of health condition studied	
Groups that have been masked		knee osteoarthritis	
No information		ICD-10 code	
Sample size		M17	
Target sample size: 15		ICD-10 code description	
Randomization (investigator's opinion)		Osteoarthritis of knee	
N/A		Primary outcomes	
Randomization description		1	
Blinding (investigator's opinion)		Description	
Not blinded		pain after TKA	
Blinding description		Timepoint	
Placebo		4 weeks, 3, 6 and 12 months after surgery	
Not used		Method of measurement	
Assignment		Using VAS questionnaire	
Single		Secondary outcomes	
Other design features		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	
Secondary Ids			
empty			
Ethics committees			
1			
Ethics committee			
Name of ethics committee			

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Abolfazl Bagherifard

Street address

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

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Email

hassanyadeh.moh@iums.ac.ir

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

City

Tehran

Province

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Postal code

3164115812

Phone

+98 912 218 8190

Email

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

Street address

Shafa Yahyaean hospital, next to the Islamic Council,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abolfazl Bagherifard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Hassanzadeh

Position

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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