

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of rehabilitation of Total knee arthroplasty patients with and without knee immobilizer brace in Imam khomeini and khatam hospitals 2017

#### Protocol summary

##### Study aim

1- Determination of the brace effect in rehabilitation of knee replacement patients 2. Improved knee replacement patients 3. Reducing pain in knee replacement patients 4. Reducing costs after knee surgery if Brace is ineffective 5- Reduction of complications after knee surgery in case of postoperative brace complication

##### Design

This is a Randomize Clinical Trial study. The title of study is "Comparison of new immobilizer brace effect on rehabilitation of Total knee arthroplasty patients in Imam Khomeini and Khatam hospitals, 2017". Study is parallel and the target sample size is seventy that will be divided to control and case groups. The case group randomly will use Immobilizer Brace after operation for 8 days. Control and case groups will be followed for 30 days. The groups will be visited 4 times include Pre-op, 1 Day Post-op, 9 Day Post-op, 30 Day Post-op. We split the patients one by one into groups with brace and without brace. We won't had any previous decision about "which patients will be in what group". this study hasn't ant allocation.

##### Settings and conduct

This study will be performed on patients with Total Knee Arthroplasty in Imam Khomeini and Khatam al-Anbia hospitals in Tehran. All of these patients will be operated by one surgeon in two hospitals. Patients will be visited on the day before the surgery and the next day in the hospital. On the 9th and 30th days after surgery, patients will be visited at the clinic. the variables will be measured in all of the visits.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 1. Fully aware of the type of intervention 2. Consent to Inclusion 3. Diseases such as Hemophilia and do not interfere with the study 4- Performing knee replacement surgery in Imam Khomeini and Khatam hospitals 5. Cooperate in the study

Exclusion criteria: 1. The patient refused to intervene and participate in the study 2. Interference effects in the study, including fracture, infection, and ... 3. Create a lack of access to any patients

##### Intervention groups

Intervention group: The patients randomly who will use Knee Immobilizer Brace after Total knee arthroplasty for 8 days. Control group: The patients randomly who won't use Knee Immobilizer Brace after Total knee arthroplasty. They can move active and passive their knee in first 8 days after surgery.

##### Main outcome variables

The variables of study: 1- Knee Range of Motion pre-op and 30th days post-op 2- Knee Society Score Pre-op and 30th days post-op 3- The day, The patient can do SLR (Straight Leg Raise) Post-op. 4- Visual Analog Scale (VAS) of pain Pre-op, First Day post-op, 9th days post-op and 30th days post-op 5-Knee Society Functional Score Pre-op and 30th days post-op. 6-The Day, The Patient can do knee Extension Post-op.

#### General information

##### Reason for update

##### Acronym

TKA and Brace

##### IRCT registration information

IRCT registration number: **IRCT20160809029286N2**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

##### Registration date

2018-02-07, 1396/11/18

##### Registrant information

##### Name

Alireza Moharrami

**Name of organization / entity****Country**

Iran (Islamic Republic of)

**Phone**

+98 21 4401 7418

**Email address**

a-moharrami@student.tums.ac.ir

**Recruitment status****Recruitment complete****Funding source**

joints reconstruction research center in Imam Khomeini Hospital

**Expected recruitment start date**

2018-01-07, 1396/10/17

**Expected recruitment end date**

2018-03-20, 1396/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of rehabilitation of Total knee arthroplasty patients with and without knee immobilizer brace in Imam khomeini and khatam hospitals 2017

**Public title**

Comparison of rehabilitation of Total knee arthroplasty patients with and without knee immobilizer brace in Imam khomeini and khatam hospitals 2017

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

Fully aware of the type of intervention Consent to Inclusion diseases such as hemophilia and do not interfere with the study performing knee replacement surgery in Imam Khomeini and Khatam hospitals cooperate in the study

**Exclusion criteria:**

The patient refused to intervene and participate in the study interference effects in the study, including fracture, infection, and ... Create a lack of access to any patients

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

the TKA patients enter to each groups with

randomization. they do not know which groups are for their. randomization is individual and simple and we don't give their any detail about which groups are for their. We split the patients one by one into groups with brace and without brace. We do not have a previous decision on which patients are in what group.

**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**

Ethics committee of Tehran University of Medical science- Imam khomeini hospital

**Street address**

Ethics committee, Imam Khomeini complex Hospital(Tehran university of Medical Science) , keshavarz Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2018-01-06, 1396/10/16

**Ethics committee reference number**

8911215163 (شماره نامه) : IR.TUMS.IKHC.REC.1396.4154)

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

Total Knee Arthroplasty

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Extension

**Timepoint**

First Day Post-op, 9th Days Post-op, 30th Days Post-op

**Method of measurement**

Physical Exam (yes/no)

## 2

### **Description**

Range of Motion

### **Timepoint**

Pre-op, 30th Days Post-op

### **Method of measurement**

Goniometer

## 3

### **Description**

Pain

### **Timepoint**

Pre-op, First Day Post-op, 9th Days Post-op, 30th Days Post-op

### **Method of measurement**

VAS (visual analog scale) 1-10

## 4

### **Description**

Knee Society Score

### **Timepoint**

Pre-op, 30th Days Post-op

### **Method of measurement**

Knee Society Scoring (0-100)

## 5

### **Description**

Knee Society Functional Score

### **Timepoint**

Pre-op, 30th Days Post-op

### **Method of measurement**

Knee Society Functional Scoring (0-100)

## 6

### **Description**

SLR (straight leg raise)

### **Timepoint**

First Day Post-op, 9th Days Post-op, 30th Days Post-op

### **Method of measurement**

SLR Test (yes/no)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

using new immobilizer Brace post operation for 8 days

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini complex hospital

##### **Full name of responsible person**

Dr seyed mohammad javad Mortazavi

##### **Street address**

Tohid square , Tehran, Iran

##### **City**

Tehran

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Imamhospital@tums.ac.ir

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<http://ikhc.tums.ac.ir/>

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Khatam alanbiya hospital

##### **Full name of responsible person**

Dr SM javad Mortazavi

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vali-e-asr st, Tehran, Iran

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info@khatamhospital.org

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<http://www.khatamhospital.org>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

joint reconstruction research center

##### **Full name of responsible person**

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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**  
joint reconstruction research center  
**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**  
Persons

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Alireza Moharrami  
**Position**  
Medical student  
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Medical doctor  
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## Person responsible for scientific inquiries

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**Position**  
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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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

**Title and more details about the data/document**

The effect of brace in rehabilitation of patients with knee replacement in Imam Khomeini and Khatam Alaniba Hospitals in Tehran, 2017-2018

**When the data will become available and for how long**

the data will be published in April 2018

**To whom data/document is available**

MD

**Under which criteria data/document could be used**

not any more

**From where data/document is obtainable**

email : a.moharramy@gmail.com

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

in 2 weeks

**Comments**