Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Alireza Moharrami

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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
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
Web page address
http://ikhc.tums.ac.ir/

2

Recruitment center
Name of recruitment center
Khatam alanbiya hospital
Full name of responsible person
Dr SM javad Mortazavi
Street address
vali-e-asr st, Tehran, Iran
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Postal code
1419733141
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Email
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Web page address
http://www.khatamhospital.org

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
joint reconstruction research center
Full name of responsible person
Dr sm javad Mortazavi
Street address
Imam Khomeini hospital, Tehran
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Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000

Email
Imamhospital@tums.ac.ir
Web page address
http://www.ikch.tums.ac.ir
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
Latest degree
Medical doctor
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Web page address

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