

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the optimal area of surgical incision for total knee arthroplasty in patients with old scars

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the best area for surgical incision of complete knee joint replacement in patients with old scars in Hazrat Rasool Akram Hospital.

Design

Clinical trial of control group with randomized double-blind parallel groups with 44 patients

Settings and conduct

In the control group, patients will be subjected to a new incision at a safe distance of 7 to 8 cm from the old scar by the standard method, and in the intervention group, patients will undergo an incision at a closer distance on the patient's knee. The results of the study will be evaluated and compared in terms of the possible occurrence of any skin complication in patients and the general results of surgery in the time intervals of 1 week, 2 weeks and 1 month after surgery.

Participants/Inclusion and exclusion criteria

The patient is a candidate for complete knee replacement surgery. Age over 15 years in a patient The patient has an old scar caused by a previous surgical incision or lesion in the skin of the knee

Intervention groups

The incision site in both groups. In the intervention group, the incision site is cut midline regardless of the scar site, but in the control group, the incision site is incised at a distance of 8 cm from the scar site.

Main outcome variables

Age / sex / old scar / length of old scar / distance from surgical incision to old scar / type of previous surgery / skin necrosis after surgery

Last update: **2021-08-08, 1400/05/17**

Update count: **0**

Registration date

2021-08-08, 1400/05/17

Registrant information

Name

Ali Yeganeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 9233

Email address

yeganeh471@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the optimal area of surgical incision for total knee arthroplasty in patients with old scars

Public title

optimal area of surgical incision in total knee arthroplasty patients with old scars

Purpose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039883N2**

Registration date: **2021-08-08, 1400/05/17**

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for total knee arthroplasty Have an old surgical scar on the knee within the surgical incision area
Age over 15 years in pateint

Exclusion criteria:
Patients' dissatisfaction with participating in this research project

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the participants in the study using inclusion and non-inclusion criteria, to prevent the occurrence of bias in the selection of participants to intervention and control groups, we will use the randomization method to minimize the opinion of researchers in selecting participant to study groups. The block randomization method was used in this study. The size of the blocks is considered to be four and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A and B. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.

Blinding (investigator's opinion)
Double blinded

Blinding description
After obtaining informed consent and explaining that the selection in each group is done randomly by the program and how each group is done, the participants are divided into two groups without knowing which group they are in Obviously, if any of the participants object, it will be removed from the study list and routine treatment will be performed according to the protocol And the analyzer does not know which group each patient is in.

Placebo
Not used

Assignment
Parallel

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

Tehran Hemat Highway next to Milad Tower. 14535

City

Tehran

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Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2021-03-16, 1399/12/26

Ethics committee reference number

ir.iums.rec.1399.1450

Health conditions studied

1

Description of health condition studied

Determining the best area for a total knee arthroplasty surgical incision in patients with an old scar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Skin incision healing

Timepoint

Before intervention / One week after intervention / 2 weeks after intervention / One month after intervention

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who try to total knee arthroplasty regardless of the distance from the scar site with the midline approach. That is, if the previous scar site is not spaced and overlaps with our midline incision, we will continue the midline approach. Campbell's book page 456 The distance between the old and the new

incision should be at least 8 cm, but according to the mechanism of fasciomusculocotaneus flap and the method in which it is done, it seems that this amount of distance from the original incision is not necessary Did

Category

Treatment - Surgery

2

Description

Control group: Patients whose incision distance from the scar is at least 8 cm and is performed according to the book protocol

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital Tehran

Full name of responsible person

Ali Yeganeh

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sattarkhan; Niyayesh St, 14456 13131

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian, Vice Chancellor for research of Iran University of Medical Sciences

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Tehran Hemat Highway next to Milad Tower ,Iran University of Medical Sciences

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research@iums.ac.ir

Web page address

<http://iums.ac.ir/en>

Grant name

Grant code / Reference number

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

No

Title of funding source

Research of Iran 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

Iran University of Medical Sciences

Full name of responsible person

Ali Yeganeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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