Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the results of using 3 suture techniques in total knee joint replacement surgeries

Protocol summary

Study aim
The results of this study will help orthopedic surgeons and other healthcare providers, including nurses, to use the most suitable suture method to reduce scars and pain after total knee replacement surgery and improve the quality of life of patients. The results of this study can also be extended to other surgical fields.

Design
The clinical trial has a control group with parallel groups, a crossover on 96 patients.

Settings and conduct
This is a single-blind clinical trial study that will be conducted in Hamedan Ba'ath Hospital in 1402. In this study, total knee joint replacement surgical skin suture with 4 methods of tandem polystitch nylon suture, modified buried vertical mattress suture of monocryl, vertical-horizontal mattress suture The modified nylon band and the surgical suture routine (subcuticular) will be performed in Baath Hospital. The participants will not have a total knee joint replacement in the process of using sutures.

Participants/Inclusion and exclusion criteria
• Adult patients (age ≥18 years) • Having a signed informed consent form • Patients who are candidates for total knee joint replacement

Intervention groups
The first group (exam): Tandem stitch group, poly stitch, nylon bank The second group (examination): the suture group of the modified Bankh Monocryl vertical buried mattress The third group (exam): modified vertical-horizontal mattress stitch group of nylon bankh The fourth group (control): surgical suture group (subcuticular) in Baath Hospita

Main outcome variables
What is the average scar score of the patient and the satisfaction of the surgeon after the operation of total knee joint replacement with Tandem Suture Polystitch with Nylon, Modified Buried Vertical Mattress Suture, Modified vertical and horizontal mattress suture, Routine surgeon's suture (subcuticular)?

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230506058104N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date
2023-05-15, 1402/02/25

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-09, 1402/02/19
Expected recruitment end date
2023-08-10, 1402/05/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
A comparative study of the results of using 3 suture techniques in total knee joint replacement surgeries

Public title
A comparative study of the results of using 3 suture techniques in total knee joint replacement surgeries

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients (18 years or older) Having a signed informed consent form Patients who are candidates for total knee replacement

Exclusion criteria:
History of keloid scar formation Long-term use of corticosteroids Uncontrolled diabetes (Fasting blood sugar 200 mg/dL or more) Previous knee surgery Hypoalbuminemia Less than 5.3 mg/dL Anemia (Hemoglobin less than 10 mg/dL) Inflammatory joint disease (rheumatoid arthritis-psoriatic arthritis-bursitis...)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
In the first step, the samples will be divided into smokers (at least one cigarette per day) and non-smokers using the stratified sampling method. Then we determine how many smoking participants and how many non-smoking participants will be placed in the 4 groups. In the next step, we will use the block method to divide this number of smoking and non-smoking participants into groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be single blind. In this way, the participants will not receive a total knee joint replacement in the process of using sutures.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
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Approval date
2023-05-04, 1402/02/14

Ethics committee reference number
IR.UMSHA.REC.1402.102

Health conditions studied

1

Description of health condition studied
total knee joint replacement surgerie

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Scar in patient and surgeon scar evaluation questionnaire

Timepoint
2 weeks-6 weeks-3 months

Method of measurement
Patient and surgeon scar evaluation questionnaire (PoSAS) - VAS surgeon satisfaction evaluation scale

Secondary outcomes

empty

Intervention groups

1

Description
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Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamedan 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

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available