Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Surgical wound dehiscence and Infection rate in two Methods of Skin stapler and Nylon suture in Wound closure of Diabetic patients undergoing Total knee arthroplasty (TKA)

Protocol summary

Study aim

Investigating the rate of wound dehiscence and infection of surgical wound using two Methods of skin stapler and nylon thread in closing the wound of diabetic patients undergoing total knee replacement surgery

Design

Clinical trial, with control group, with parallel groups, without blinding, randomized on 120 patients. The participants will be randomly listed using computer software (RAS) into two groups of closure with nylon suture and closure with staples using permutation blocks in 15 blocks of 8.

Settings and conduct

The study will take place in the medical center of Lar city. All diabetic patients undergoing total knee arthroplasty will be operated with the same techniques and tools. All patients will be operated from sub vestus approach and with PFC sigma depuy prosthesis by one surgeon.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definitive diagnosis of diabetes through examination of tests; fasting blood sugar between 70 and 130; Exclusion criteria: History of cancer and chemotherapy, uncontrolled internal and vascular diseases; Reduction of blood albumin; Taking systemic corticosteroid drugs before surgery; Having a history of knee surgery or the presence of scars and wounds in the knee area

Intervention groups

Intervention group: Using skin stapler to close the surgical wound; Control group: using nylon suture to close the surgical wound

Main outcome variables

Wound infection, wound dehiscence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230928059543N1**
Registration date: **2024-01-12, 1402/10/22**
Registration timing: **prospective**

Last update: **2024-01-12, 1402/10/22**
Update count: **0**

Registration date

2024-01-12, 1402/10/22

Registrant information

Name

Armin Fereidouni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3753 2383

Email address

arminfereidoni@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-01, 1402/12/11

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Surgical wound dehiscence and Infection rate in two Methods of Skin stapler and Nylon suture in Wound closure of Diabetic patients undergoing Total knee arthroplasty (TKA)

Public title
Comparison of two wound closure methods after knee joint replacement in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Definitive diagnosis of diabetes through the examination of the patient's tests by an internal medicine specialist and the use of diabetes medications presence of fasting blood sugar between 70 and 130 mg/dL Age range from 40 to 90 years

Exclusion criteria:
History of cancer and chemotherapy, uncontrolled internal and vascular diseases Reduction of blood albumin Taking systemic corticosteroid drugs before surgery Having a history of knee surgery or the presence of scars and wounds in the knee area Getting infectious and viral diseases (colds and COVID-19) before and after surgery Increased blood urea Suffering from immunosuppressive diseases

Age
From **40 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be randomly assigned to two groups of closure with nylon suture and closure with staples using Random Allocation computer Software (RAS)version 4.9 (Internet address: https://random-allocation-software.software.informer.com/2.0/). Random allocation by the permutation block method is listed in 15 blocks of 8 with random allocation software, the list provided is attached to the proposal.

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 Shiraz University of Medical Sciences

Street address
5.7 side alley; 5 alley; Dolate-sharghy Blvd.; Shiraz

City
Shiraz

Province
Fars

Postal code
7167755954

Approval date
2023-11-11, 1402/08/20

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.112

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Wound infection

Timepoint
The evaluation of the results of the patient's wound in terms of the rate of wound infection will be followed up and recorded 2 to 8 weeks after the operation.

Method of measurement
Surgical wound infection checklist

2

Description
Wound dehiscence

Timepoint
The evaluation of the results of the patient's wound in terms of the rate of wound dehiscence will be followed up and recorded 2 to 8 weeks after the operation.

Method of measurement
Surgical wound dehiscence checklist

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The first intervention group includes people who use nylon thread to close their wounds after knee replacement surgery. In the first group, surgical wound closure using 2-0 nylon thread (Supalon), monofilament with polyamide-6, which is produced by Supa company in Iran, will be done in a simple interrupted manner. Skin closure will be done at a 45-degree knee bend angle.
Category
Treatment - Surgery

2

Description
Intervention group: This group includes people whose wounds will be closed with skin staples after knee joint replacement surgery. In this group, surgical wound closure will be performed using a special covidin skin surgical stapler (Appose ULC 35W).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Larestan Educational and Medical Center
Full name of responsible person
Armin Fereidouni
Street address
5.7 side alley; 5 alley; Dolate-sharghy Blvd.; Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempur
Street address
5.7 side alley; 5 alley; Dolate-sharghy Blvd.; Shiraz
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Armin Fereidouni
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Armin Fereidouni
Position

Instructor

Latest degree

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Other areas of specialty/work

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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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Study data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

By sending an email to the author responsible for the article, the data will be made available to experts in this field.

From where data/document is obtainable

People can get the study data by sending an email to Armin Feridouni (author responsible for the article). Email: arminfereidoni@yahoo.com

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

Ten days after receiving the email by the responsible author, the data will be available to the requesting person.

Comments