Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of local insulin administration on wound healing in diabetic patients who underwent surgery

Protocol summary

Study aim
Determining the effect of local insulin administration on wound healing in diabetic patients who underwent surgery

Design
Clinical trial, with parallel groups, double-blind, randomized, phase 3 on 40 patients

Settings and conduct
The current study is a randomized clinical trial that will be conducted on patients referred to Al-Zahra and Shahid Beheshti hospitals to perform laparotomy with Feinstein's standard incision. Controls will be distributed to the patient in sealed envelopes that are coded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. having diabetes, 2. Indication of laparotomy with standard Feinstein incision. 3. Receiving standard prophylactic antibiotics, 4. Declaration of informed consent to participate in the study. Criteria for not entering the study: 1. Have an underlying disease that affects the wound healing process, such as cancer and neoplasm, immunodeficiency, history of chemotherapy and radiotherapy, 2. Re-incision in similar site of previous surgery 3. Visceral injury during surgery 4. Simultaneity of another surgery, 5. The need for blood transfusion during surgery

Intervention groups
Patients in the intervention group underwent subcutaneous wound injection with regular insulin at the rate of 0.2 units per kilogram of body weight diluted with 5 cc of distilled water and then using a 5 cc syringe and insulin needle subcutaneously and uniformly for 10 Feinstein cut centimeter is injected. This injection will be done once a day on the 1st, 2nd, 3rd, 5th and 7th days after the operation.

Main outcome variables
Infection and purulent discharge, pain, necrotizing fasciitis, granulation tissue formation, wound healing time, cellulitis, bleeding, wound surface

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230116057136N1**
Registration date: **2023-05-30, 1402/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-30, 1402/03/09**
Update count: **0**

Registration date
2023-05-30, 1402/03/09

Registrant information
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Minoo Movahedi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2024-07-22, 1403/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of local insulin administration on wound healing in diabetic patients who underwent surgery

Public title
The effect of topical insulin on wound healing in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having diabetes Indication of laparotomy with standard Feinstein incision Receive standard prophylactic antibiotics Declaration of informed consent to participate in the study
Exclusion criteria:
having an underlying disease that affects the wound healing process, such as cancer and neoplasm, immunodeficiency, history of chemotherapy and radiotherapy Re-incision in similar site of previous surgery Visceral injury during surgery Simultaneity of another surgery The need for blood transfusion during surgery
Age
From **20 years** old to **80 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sequence is prepared by biostatistics specialist and using excel software, a random table for 40 patients is provided to the researcher. The randomization is based on 4 random blocks because we have two groups of comparisons. Ten blocks of 4 that will be prepared using the sequence table. The allocation of participants is done using concealment with the method of closed envelopes. In this method, the sequence table designed in the previous section is used. Because of the type of intervention (is known), there is no possibility of blindness.
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
Ethical Committee of Isfahan University of Medical Sciences
Street address
Motahari St., Shahid Dr. Beheshti Hospital
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Esfahan
Province
Isfehan
Postal code
8184853542
Approval date
2022-11-17, 1401/08/26
Ethics committee reference number
IR.MUI.MED.REC.1401.298

Health conditions studied

1

Description of health condition studied
Laparotomy candidate patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Infection and purulent discharge
Timepoint
One week, two weeks, four weeks after cutting
Method of measurement
Physical examination and history

2

Description
Pain
Timepoint
One week, two weeks, four weeks after cutting
Method of measurement
Physical examination and history

3

Description
Necrotic fascism
Timepoint
One week, two weeks, four weeks after cutting
Method of measurement
Physical examination and history

4

Description

Formation of granulation tissue

Timepoint

One week, two weeks, four weeks after cutting

Method of measurement

Physical examination and history

5

Description

Wound healing time

Timepoint

One week, two weeks, four weeks after cutting

Method of measurement

Physical examination and history

6

Description

Cellulite

Timepoint

One week, two weeks, four weeks after cutting

Method of measurement

Physical examination and history

7

Description

Bleeding

Timepoint

One week, two weeks, four weeks after cutting

Method of measurement

Physical examination and history

8

Description

Wound surface

Timepoint

One week, two weeks, four weeks after cutting

Method of measurement

Physical examination and history

Secondary outcomes

1

Description

Fasting blood sugar test

Timepoint

Before injection and then at an interval of one hour and 4 hours after injection

Method of measurement

Using a glucometer

2

Description

Readmission

Timepoint

Intervals of one week, two weeks, four weeks after cutting

Method of measurement

Patient file

Intervention groups

1

Description

Intervention group: Patients in the intervention group underwent subcutaneous wound injection with regular insulin at the rate of 0.2 units per kilogram of body weight diluted with 5 cc of distilled water and then using a 5 cc syringe and insulin needle subcutaneously and uniformly for 10 Feinstein cut centimeter is injected.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will be injected with distilled water (with maximum effort to avoid pain and without any anesthetic)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mino Movahdi

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2

Recruitment center

Name of 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?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
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Position
Associate professor, specialist doctor of the academic staff
Latest degree
Specialist
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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
Undecided - It is not yet known if there will be 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