

# 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

##### Name

Minoov Movahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3620 2020

##### Email address

movahediminoov1345@gmail.com

##### 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 Feinsein 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

**City**

Esfahan

**Province**

Isfahan

**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 Feinsteint 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

##### **Street address**

Motahari Street, Shahid Beheshti Hospital

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

8184853542

##### **Phone**

+98 31 3236 7005

##### **Email**

movahedi@med.mui.ac.ir

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Al-Zahra Hospital

##### **Full name of responsible person**

Dr. Mino Movahdi

##### **Street address**

Esfahan

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3620 2020

**Email**  
alzahra@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr. Mino Movahdi  
**Street address**  
Isfahan province, Isfahan city, Hazar Jarib St  
**City**  
Esfahan  
**Province**  
Isfahan  
**Postal code**  
۷۳۴۶۱-۸۱۷۴۶  
**Phone**  
+98 31 3668 0048  
**Email**  
education@med.mui.ac.ir

#### 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**  
Dr. Mino Movahdi  
**Position**  
Associate professor, specialist doctor of the academic staff  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Hazar Jarib Street, Isfahan University of Medical Sciences, Faculty of Medicine  
**City**  
Esfahan

**Province**  
Isfahan  
**Postal code**  
81746  
**Phone**  
+98 31 3620 1274  
**Email**  
internal@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr. Mino Movahdi  
**Position**  
Associate professor, faculty specialist doctor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Isfahan - Azadi Square - Isfahan University  
**City**  
Esfahan  
**Province**  
Isfahan  
**Postal code**  
۸۱۷۴۶۷۳۴۶۱  
**Phone**  
+98 31 3793 2128  
**Email**  
moavenat-amouzeshti@dean.ui.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr. Mino Movahdi  
**Position**  
Associate professor, medical specialist of the academic staff  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Isfahan - Azadi Square - Isfahan University  
**City**  
Esfahan  
**Province**  
Isfahan  
**Postal code**  
۸۱۷۴۶۷۳۴۶۱  
**Phone**  
+98 31 3793 2288  
**Email**  
movahedi@med.mui.ac.ir

## **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