

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluation of a new protocol for controlling blood glucose and comparing it with old strategies for controlling blood glucose in patients who hospitalized in infectious ward

#### Protocol summary

##### Study aim

Evaluation of a new protocol for controlling blood glucose in patients who hospitalized in infectious ward

##### Design

A non-randomized clinical trial with parallel group

##### Settings and conduct

Patients with diabetes who admitted to the Infectious Diseases department of Loghman Hakim Hospital, Tehran, included. After considering inclusion and not-inclusion criteria, patients divided into two groups. The first group receives short-acting insulin by sliding scale before each meal, and in the second group, patients receive a combination of short-acting and long-acting insulin based on the needed daily insulin dose.

##### Participants/Inclusion and exclusion criteria

Patients over the 18 years old with diabetes who have been admitted in infectious ward due to pneumonia, cellulitis, or diabetic foot infection included. These patients were used subcutaneous insulin. Pregnant women, patients with end stage renal disease, patients who used intravenous insulin, surgical patients, and patients receiving total parental nutrition are not included.

##### Intervention groups

The first group treat with insulin by sliding scale and receive different doses of short acting insulin based on the level of glucose before meals. The second group, based on the calculated daily insulin, receive certain dose of insulin which is combination of short and long-acting insulin twice a day.

##### Main outcome variables

Blood glucose level; Fever; Length of hospitalization.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20130917014693N9**

Registration date: **2019-08-15, 1398/05/24**

Registration timing: **retrospective**

Last update: **2019-08-15, 1398/05/24**

Update count: **0**

#### Registration date

2019-08-15, 1398/05/24

#### Registrant information

##### Name

Zahra Sahraei

##### Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

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#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2017-04-04, 1396/01/15

#### Expected recruitment end date

2017-08-22, 1396/05/31

#### Actual recruitment start date

2017-04-04, 1396/01/15

#### Actual recruitment end date

2017-08-22, 1396/05/31

#### Trial completion date

2017-09-06, 1396/06/15

#### Scientific title

Evaluation of a new protocol for controlling blood glucose and comparing it with old strategies for controlling blood glucose in patients who hospitalized in infectious ward

#### Public title

Evaluation of a new protocol for controlling blood glucose in hospitalized patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with diabetes mellitus Age more than 18 years ago Patients under subcutaneous insulin regimen Patients who hospitalized in infectious diseases ward due to pneumonia, cellulitis, and diabetic foot infection

##### Exclusion criteria:

Pregnant women Surgical patients Patients on intravenous insulin Patients with end stage renal disease Patients on total parental nutrition Patients who did not sign the patient informed consent form

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **108**

Actual sample size reached: **90**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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

Research Ethics Committee of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

##### Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

#### Approval date

2017-03-07, 1395/12/17

#### Ethics committee reference number

IR.SBMU.PHNM.1395.606

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

### 2

#### Description of health condition studied

Pneumonia

#### ICD-10 code

B95.3

#### ICD-10 code description

Streptococcus pneumoniae as the cause of diseases classified elsewhere

### 3

#### Description of health condition studied

cellulitis

#### ICD-10 code

L03.03

#### ICD-10 code description

Cellulitis of toe

### 4

#### Description of health condition studied

Diabetic foot infection

#### ICD-10 code

Z86.31

#### ICD-10 code description

Personal history of diabetic foot ulcer

## Primary outcomes

### 1

#### Description

Blood glucose level

#### Timepoint

Every six hours

#### Method of measurement

Glucometer

## Secondary outcomes

### 1

#### Description

Fever

**Timepoint**

Every six hours

**Method of measurement**

Mercury Thermometer

**2****Description**

Duration of hospitalization

**Timepoint**

At discharged

**Method of measurement**

Patient record

**Intervention groups****1****Description**

Intervention group: In this group the needed daily insulin calculate. This dose includes short acting insulin (Regular, Exir Company) and long action insulin (NPH, Exir Company). The patients will receive this combined dose as twice day by subcutaneous injection. This dose will be administered every morning and every evening. This protocol will be continued in all of hospitalization duration.

**Category**

Treatment - Drugs

**2****Description**

Control group: In this group, the blood glucose level of patients will be determined before each essential meals by glucometer. Then, different doses of short acting insulin (Regular, Exir Company) will be administered by subcutaneous injection. This protocol will be continued in all of hospitalization duration.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Loghman-hakim hospital

**Full name of responsible person**

Zahra Sahraei

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Makhsos St, South Karegar Ave, Tehran, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nima Naderi

**Street address**

Faculty of Pharmacy-Niyayesh intersection-Valiasr St

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Sahraei

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

**Contact**

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Saffaei

**Position**

Resident

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Primary outcome data after making unrecognizable will be released.

**When the data will become available and for how long**

Six months after publishing the results primary outcome data will be released.

**To whom data/document is available**

Researchers after allowance of corresponding author could have the permission to have the data.

**Under which criteria data/document could be used**

Performing any analysis will be allowed only with the permission of corresponding author.

**From where data/document is obtainable**

Corresponding researcher

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

After requesting to reach data, corresponding author will check the allowance, then the researcher will be informed about it.

**Comments**