

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)

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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

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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

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