

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison the effectiveness of basal-plus and basal-bolus regimens in patients with type 2 diabetes

Protocol summary

Study aim

Comparison the effectiveness of basal-plus and basal-bolus regimens in patients with type 2 diabetes

Design

A clinical trial with two parallel intervention groups, not blinded, randomized

Settings and conduct

Participants are people with type 2 diabetes who referred to one of the following centers: Diabete Research Center, Khatam al-Anbia Clinic and Imam Ali Clinic in Yazd. Among patients who meet inclusion and exclusion criteria, there were 80 samples selected based on G Power statistical formula and randomly divided into 2 equal groups. All variables were measured in both groups before the onset of insulin regimens. Subsequently, one group was treated by Basal-plus regimen and the other by Basal-bolous for 3 months. Finally after the end of treatment, all variables were again measured in both groups and the effect of these regimens were determined by the improvement of 3 variables; Fasting Blood Sugar(FBS), two hour postprandial(2hpp), Hemoglobin A1c (HbA1c).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients whom their blood glucose level is not controlled by eatable drugs and we decided to begin insulin therapy; patients with HBA1c more than 8.5. Exclusion criteria: Patients who use glucocorticoids; patients with liver dysfunction and renal dysfunction(Creatinine more than 3); patients with history of diabetic ketoacidosis; pregnant women ; mental retard patients who are not able to assent.

Intervention groups

The total population of the study were randomly divided into two equal groups and formed intervention groups. Subsequently, one group was treated by Basal-plus regimen and the other by Basal-bolous for 3 months.

Main outcome variables

Fasting blood sugar; Two hour postprandial glucose; Hemoglobin A1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140819018858N8**

Registration date: **2018-11-16, 1397/08/25**

Registration timing: **retrospective**

Last update: **2018-11-16, 1397/08/25**

Update count: **0**

Registration date

2018-11-16, 1397/08/25

Registrant information

Name

Masoud Rahmanian

Name of organization / entity

Diabet Research Center, Yazd Shahid Sadughi University Of Mdical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 1728 0215

Email address

rahmanian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Yazd University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-08-22, 1395/06/01

Actual recruitment end date

2017-08-02, 1396/05/11

Trial completion date

2017-11-02, 1396/08/11

Scientific title

Comparison the effectiveness of basal-plus and basal-bolus regimens in patients with type 2 diabetes

Public title

Comparison the effect of two different insulin regimens in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients whom their blood glucose level is not controlled by eatable drugs and we decided to begin insulin therapy
Patients with HBA1C> 8.5

Exclusion criteria:

Patients who use glucocorticoids
Patients with liver disease and renal dysfunction (Cr>3)
Patients with positive history of diabetic ketoacidosis
Patients who are pregnant
Mental retard patients who are not able to assent

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

randomized block design: four in block size in intervention groups

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 Shahid Sadoughi University of Medical Science

Street address

Shahid Sadoughi boulevard, Bahonar square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8917693571

Approval date

2016-08-01, 1395/05/11

Ethics committee reference number

IR.SSU.REC.1395.84

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Two hour postprandial sugar

Timepoint

First of study, one month, two months and three months after starting Insulin regimen

Method of measurement

By checking blood samples of the patients

2**Description**

Fasting blood sugar

Timepoint

First of study, one month, two months and three months after starting Insulin regimen

Method of measurement

By checking blood samples of the patients

3**Description**

Hemoglobin A1c

Timepoint

First of study, one month, two months and three months after starting Insulin regimen

Method of measurement

By checking blood samples of the patients

Secondary outcomes

empty

Intervention groups

1

Description

In basal bolus regimen we add prandial insulin before every three major meals in a day, this regimen continues for three months and the insulin units are decided based on every patient's first FBS and 2hpp.

Category

Treatment - Drugs

2

Description

In basal plus regimen we add prandial insulin before the major meal in a day, this regimen continues for three months and the insulin units are decided based on every patient's first FBS and 2hpp.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabete Research Center

Full name of responsible person

Samaneh Jam

Street address

Talar Honar alley, Bahonar square, Yazd, Iran

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2

Recruitment center

Name of recruitment center

Yazd Imam Ali clinic

Full name of responsible person

Fatemeh Bidmeshki

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Imam Ali clinic, Navab Safavi boulevard, Yazd, Iran

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3

Recruitment center

Name of recruitment center

Yazd Khatam Al-Anbia Clinic

Full name of responsible person

Fatemeh Karimi Yazdi

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Khatam Al-Anbia Clinic, Taleghani boulevard, Mahdiyeh square, Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mehrpavar Hooshang

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Shahid Sadoughi University of Medical Sciences, Bahonar square, Yazd, Iran

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Email

ah.mehrpavar@gmail.com

Grant name

1255001

Grant code / Reference number

30303000

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Bidmeshki

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoud Rahmanian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Parisa Yazdani Elahabadi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Fax**Email**

parisa_hiti@yahoo.com

Web page address

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

Potentially, all data is shareable after anonymization.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Raw data is provided to researchers for secondary analysis confidentially.

From where data/document is obtainable

Masoud Rahmanian 09133592836

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

Submit a proposal from prestigious academic institution

Comments