Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 35 1728 0215

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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
Street address
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
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ah.mehrparvar@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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Assistant Professor

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Endocrinology

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Person responsible for updating data

Contact

Name of organization / entity
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General Practitioner

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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