

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Mobile Based Bolus Calculator and Multiple Daily Injections Method for Glycemic Control in Diabetic Patients

Protocol summary

Summary

We investigate the effect of carbohydrate counting by mobile based bolus calculator on glycemic control in adult diabetic patients. Inclusion criteria included patients with more than one year of type one or two diabetes duration who receive treatment with multiple daily injections technique, with long- and rapid-acting insulin analog and exclusion criteria included gastroparesis or celiac disease, using of or former training in carbohydrate counting and problem with using of mobile programs. The 60 Subjects were chosen from diabetic patients who referred to the endocrinology clinic of Noor Hospital (Isfahan, Iran) on year 2013-2014. After screening the subjects were divided into two groups of carbohydrate counting with mobile based bolus calculator or treatment as usual with multiple daily injections method, with simple randomization. The study was performed in a 12 weeks period. Patients in the control arm used multiple daily injections technique as usual by estimating the premeal insulin doses and using correction boluses empirically. In the carbohydrate counting arm, patients used an application which was installed on their mobile phone for measuring the needed insulin dose for each meal. The mean blood glucose level and mean HbA1c were assessed before and just after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502011181N2**

Registration date: **2015-02-06, 1393/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-06, 1393/11/17

Registrant information

Name

Mansour Siavash

Name of organization / entity

Isfahan Endocrine and Metabolism Research Center

Country

Iran (Islamic Republic of)

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+98 31 1222 0998

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-01-02, 1392/10/12

Expected recruitment end date

2015-01-01, 1393/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Mobile Based Bolus Calculator and Multiple Daily Injections Method for Glycemic Control in Diabetic Patients

Public title

Mobile Based Bolus Calculator for Diabetes Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:18-65 years aged; more than one year of type one or two diabetes duration; treatment with

multiple daily injections technique, with long- and rapid-acting insulin analog. Exclusion criteria: any serious medical condition that may interfere with safe study participation; current lactation, pregnancy or inadequate contraception; gastroparesis or celiac disease; using of or former training in carbohydrate counting; problem with using of mobile programs.

Age

From **16 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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

Isfahan University of Medical Sciences

Street address

Hezar jerib Street

City

Isfahan

Postal code

Approval date

2013-10-15, 1392/07/23

Ethics committee reference number

392512

Health conditions studied

1

Description of health condition studied

Insulin-dependent diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Mean blood glucose

Timepoint

At screening and and after 12 weeks

Method of measurement

Labratory data

2

Description

Mean HbA1c

Timepoint

At screening and and after 12 weeks

Method of measurement

Labratory data

Secondary outcomes

1

Description

Hypoglycemia

Timepoint

Daily up to 12 weeks

Method of measurement

Laboratory Data

Intervention groups

1

Description

Intervention group: Patients used multiple daily injections technique with aid of an application which was installed on their mobile phone or tablet for measuring the needed insulin dose for each meal.

Category

Treatment - Drugs

2

Description

Control group: Patients used multiple daily injections technique as usual by estimating the premeal insulin doses and using correction boluses empirically.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology clinic of Noor Hospital

Full name of responsible person

Mohsen Taherian

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr Peyman Adibi
Street address
Hezar Jerib Street
City
Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty