

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

effects of acarbose in metabolic control of patients with diabetes mellitus

Protocol summary

Summary

Introduction: Acarbose is an intestinal α -glucosidase inhibitor that delays absorption of carbohydrates, the aim of this study was to investigate the effect of administration of acarbose on glycemic & lipid parameters & daily insulin requirements & its tolerance in type 1 diabetic patients. Methods: This was a randomized double blind placebo controlled study, Entry criteria: type 1 diabetes, at least from 1 year before & $HbA1C \geq 7.5\%$, exclude criteria: $Cr \geq 2$, partial GI obstruction, IBD. 45 patients were randomized to acarbose or placebo for 12 weeks; dosing of acarbose was 25 mg t.d.s for 2 weeks & then 50 mg for 10 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102165844N1**

Registration date: **2011-04-17, 1390/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-17, 1390/01/28

Registrant information

Name

Shiva Shahnazari

Name of organization / entity

Qazvin university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 28 1336 0084

Email address

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Recruitment status

Recruitment complete

Funding source

vice- cancellor of Qazvin medical science university

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effects of acarbose in metabolic control of patients with diabetes mellitus

Public title

effects of Acarbose on type 1 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: type 1 diabetes, at least from 1 year before & $HbA1C \geq 7.5\%$, exclusion criteria: $Cr \geq 2$, partial GI obstruction, IBD.

Age

To **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin university of medical science

Street address

Qazvin

City

Qazvin

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

28/30/3919

Health conditions studied

1

Description of health condition studied

type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

post prandial glucose

Timepoint

2 hours after each meal

Method of measurement

laboratory kit and Saccharimeter

Secondary outcomes

1

Description

HbA1C

Timepoint

monthly

Method of measurement

laboratory kit

Intervention groups

1

Description

acarbose administration 25 mg TDS 2 weeks then 50mg 10 weeks

Category

Treatment - Drugs

2

Description

placebo administration 25 mg TDS 2 weeks then 50mg 10 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic Of Endocrine Diseases

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Reaserch of Qazvin University of Medical Science

Full name of responsible person

Dr Saeed Asefzade

Street address

Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Reaserch of Qazvin University of Medical Science

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

Qazvin University of Medical Science

Full name of responsible person

Shiva Shahnazari

Position

Resident of Internal Diseases

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Web page address

Person responsible for updating data

Contact

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