Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The evaluation of the effect of verapamil on insulin resistance and fasting blood sugar

Protocol summary

Summary

Objectives: we evaluate the effect of verapamil on diabetes in the present study. Design: Through a placebo-control double blind randomized clinical trial of phase 1, 75 diabetic patients with high blood pressure from three endocrine and heart clinics are selected and classified into three equal groups. Setting and conduct: Blood fasting sugar and HbA1c and C peptide and insulin are measured by blood test and the results of the beginning and the end of the study are compared. Participants: Type two diabetic patients with systolic blood pressure greater than 140 and less than 160 mmHg or with diastolic blood pressure greater than 90 mmHg. Intervention: Intervention group take verapamil and placebo group take amlodipin and control group do not take any kind of drugs for 8 weeks. Main outcome measures: Primary outcome variables are the changes of fasting blood sugar. Secondary outcome variables are the changes of HbA1c.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100925895N5**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Afsaneh Talaei

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3612

Email address

talaei@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of verapamil on insulin resistance and fasting blood sugar

Public title

The effect of verapamil on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type two diabetes; systolic blood pressure greater than 140 and less than 160 or diastolic blood pressure greater than 90 mmHg; age between 25-75 years old; intake of any oral drugs of diabetes; HbA1c between 7-8.5% Exclusion criteria: Low blood pressure; heart and brain disease; pregnancy; lactation; plan to pregnancy; intake of insulin; drugs such as contraceptive or etrogen or testosterone during past three months; chronic disease such as lung, renal, liver or GI; HbA1c between 7-8.5%; systolic blood pressure

greater than 160 mmHg

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Amialmomenin Hospital, Baseej Square

City

Arak

Postal code

3848176941

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.ARAKMU.REC.1395.146

Health conditions studied

1

Description of health condition studied

Insulin Resistance

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

The changes of insulin resistance

Timepoint

The beginning of the study, After 8 weeks

Method of measurement

Blood examination test

2

Description

The changes of fasting blood sugar

Timepoint

The beginning of the study, After 8 weeks

Method of measurement

Blood examination test

Secondary outcomes

1

Description

The changes of blood pressure

Timepoint

The beginning of the study, After 8 weeks

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: One tab of verapamil, 40 mg, twice a day, oral, for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo group: One tab of amlodipin, 5, mg, once a day, oral, for 8 weeks

Category

Treatment - Drugs

3

Description

Control group: Without usage of any drugs for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Afsaneh Talaei

Street address

Amiralmomenin Hospital, Baseej Square

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafeie
Street address
Arak University of Medical Sciences, Baseej Square
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Arak 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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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