

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of verapamil on GLP-1R in type 2 diabetic patients receiving metformin and sitagliptin

Protocol summary

Study aim

Effect of verapamil on GLP-1R in type 2 diabetic patients receiving metformin and sitagliptin

Design

Two arm parallel group randomised trial with blinded

Settings and conduct

A study on diabetes is performed in Ahwaz Golestan Hospital in a randomized, double blind clinical trial, The study compares the effect of verapamil and placebo in two parallel groups of 23 patients

Participants/Inclusion and exclusion criteria

Signature of consent by patients Age between 20 and 65 years Elapsed at least three months from detection of T2DM Baseline A1c <8.5% Pregnancy and lactation Uncompensated heart failure myocardial infarction or evidence of ischemic heart disease or other serious cardiac disease within the 12 weeks before randomization History of epilepsy, cancer, cystic fibrosis, sickle cell anemia, peripheral vascular disease or cerebrovascular disease known left ventricular dysfunction hypotension (systolic pressure <90 mm Hg)

Intervention groups

Intervention group: Verapamil effect on expression frequency of TXNIP, miR-204 and GLP-1 receptor Control group: The effect of placebo on the above items

Main outcome variables

Frequency of expression of GLP-1R mRNA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180417039339N1**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **prospective**

Last update: **2018-08-07, 1397/05/16**

Update count: **0**

Registration date

2018-08-07, 1397/05/16

Registrant information

Name

farrokh ramesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8382

Email address

ramesh.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of verapamil on GLP-1R in type 2 diabetic patients receiving metformin and sitagliptin

Public title

Effect of verapamil on sitagliptin efficacy in diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signature of consent by patients Age between 20 and 65 years Elapsed at least three months from detection of

T2DM Baseline A1c <8.5%

Exclusion criteria:
 Pregnancy and lactation Uncompensated heart failure myocardial infarction or evidence of ischemic heart disease or other serious cardiac disease within the 12 weeks before randomization History of epilepsy, cancer, cystic fibrosis, sickle cell anemia, peripheral vascular disease or cerebrovascular disease known left ventricular dysfunction hypotension (systolic pressure <90 mm Hg) PR interval prolongation on EKG or any bradyarrhythmia (e.g. sick sinus syndrome, AV block) Wolff-Parkinson-White [WPW] syndrome Lown-Ganong-Levine syndrome Concomitant use of drugs that affect blood glucose levels Untreated hypothyroidism or active Graves' disease with hyperthyroidism Serum creatinine >1.5 mg/dl ,GFR<60 Currently receiving insulin therapy Total bilirubin , Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 1.5 x ULN Hypersensitivity to verapamil or any component of the formulation

Age
 From **20 years** old to **65 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
 Target sample size: **46**
 Actual sample size reached: **46**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Method of randomization: block Unit of randomization : individual Randomization strata in stratified randomization:HbA1C , BMI Tools used in randomization : sealed envelopes How the random sequence was built: table of random numbers Whether of not allocation concealment was carried out:Sealed envelopes will be opaque

Blinding (investigator's opinion)
 Double blinded

Blinding description
 participants, principle investigator, data and safety monitoring board

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 The Ethics Committee of the Jundishapur University of Medical Sciences
Street address
 Esfand Ave, Farvardin Blvd, Golestan
City
 Ahvaz
Province
 Khouzesan
Postal code
 61357-15794
Approval date
 2018-07-02, 1397/04/11
Ethics committee reference number
 IR.AJUMS.REC.1397.284

Health conditions studied

1

Description of health condition studied
 Diabetes mellitus
ICD-10 code
 E08
ICD-10 code description
 Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
 Frequency of expression of GLP-1R mRNA
Timepoint
 Before the intervention begins,Days 10,20,30 and 90
Method of measurement
 Real-time PCR

2

Description
 Frequency of expression of miR-204
Timepoint
 Before the intervention begins,Days 10,20,30 and 90
Method of measurement
 Real-time PCR

3

Description
 Frequency of expression of TXNIP mRNA
Timepoint
 Before the intervention begins,Days 10,20,30 and 90
Method of measurement
 Real-time PCR

Secondary outcomes
 empty

Intervention groups

1

Description

Intervention group: Verapamil 40mg , 3 times a day for 3 months

Category

Treatment - Drugs

2

Description

Control group: Placebo ,3 times a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Farrokh Ramesh

Street address

Farvardin Blvd, Golestan Hospital

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Esfand Ave, Farvardin Blvd, Golestan

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61359-39937

Email

badavi/m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farrokh Ramesh

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Farrokh Ramesh

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available