

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of Cuminum cyminum extract, Resvin and Vitamin C on Antioxidant parameters, Lipids profile , Ghrelin and several biochemical indices in type 2 Diabetic patients

#### Protocol summary

##### Summary

In this double blind clinical trial study, both the investigator or the participant are blind to the nature of the treatment, the participant is receiving . 160 patients from Isfahan diabetes clinic after interview and completing satisfaction's form and according to the entry and exit criteria (Entrance scale: diabetics and range of age 30 up to 50/ Exit scale: smoking, having the underlying disease and other metabolic disorders, alcohol consumption, consumption of other supplements and drugs) will be selected and will be divided to four groups, randomly. All patients during the study, will consume their prescribed drug (Metformin) according to the routine procedure , the first group will receive the extract of Cumin, second group will receive the Rezvin supplement and third group will receive Vitamin c. Fourth group as control group will receive placebo (oral gelatin capsules). At the beginning of the study and after 60 days ( consuming supplements in each group) , from all groups participants , 10 CC of venous blood in fasting status will be taken. On samples, FBS beside tests for Lipid profile, Apo A , Apo B, Gamma glutamyl transferase, Iron ,HBA1c, Glutathione peroxidase, Superoxide dismutase, Glutathione reductase, and Xanthine oxidase, Ghrelin, Paraaxonase, Total antioxidant capacity , MDA, Glutathione will be measured. We hope with affirmation of the assumptions, we could see an improvement by using natural antioxidant supplements and herbal products to deal with the destructive effects of Free radicals and oxidative stress in Diabetic patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014100619420N1**  
Registration date: **2014-11-21, 1393/08/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-21, 1393/08/30

##### Registrant information

###### Name

Mohammad Hosein Gharib

###### Name of organization / entity

Shahrekord University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3661 9867

###### Email address

mohogharib@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Shahrekord University of Medical Science

##### Expected recruitment start date

2014-11-06, 1393/08/15

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Cuminum cyminum extract, Resvin and Vitamin C on Antioxidant parameters, Lipids profile , Ghrelin and

several biochemical indices in type 2 Diabetic patients

**Public title**

Effect of Cuminum cyminum extract, Resvin and Vitamin C in type 2 Diabetic patients

**Purpose**

Other

**Inclusion/Exclusion criteria**

inclusion criteria:Diabetic patient, range of age 30 up to 50 exclusion criteria :smoking, alcoholic patient,have another metabolic or outline disease; use of other drugs or supplements

**Age**

From **30 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**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**

Morals committee of Shahrekord University of Medical Science

**Street address**

Morals committee of Shahrekord University of Medical Science, Shahrekord University of Medical Science, Rahmatieh, Shahrekord

**City**

Shahrekord

**Postal code**

8815713471

**Approval date**

2014-09-23, 1393/07/01

**Ethics committee reference number**

1393-8-29

**Health conditions studied****1****Description of health condition studied**

Diabetics type 2

**ICD-10 code**

E11

**ICD-10 code description**

Non insulin dependent diabetes mellitus

**Primary outcomes****1****Description**

Total antioxidant capacity

**Timepoint**

before intervention and 2 month after intervention

**Method of measurement**

blood analysis

**2****Description**

Ghrelin

**Timepoint**

before intervention and 2 month after intervention

**Method of measurement**

blood analysis

**Secondary outcomes****1****Description**

Cholestrol

**Timepoint**

before intervention and 2 month after intervention

**Method of measurement**

blood analysis

**2****Description**

Glucose

**Timepoint**

before intervention and 2 month after intervention

**Method of measurement**

blood analysis

**3****Description**

Triglyceride

**Timepoint**

before intervention and 2 month after intervention

**Method of measurement**

blood analysis

**4****Description**

HDL

**Timepoint**

before intervention and 2 month after intervention  
**Method of measurement**  
blood analysis

## 5

**Description**  
LDL

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 6

**Description**  
Apo A

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 7

**Description**  
Apo B

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 8

**Description**  
Fe

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 9

**Description**  
Weight

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
standard scale

## 10

**Description**  
Blood pressure

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
standard barometer

## 11

**Description**  
HbA1c

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 12

**Description**  
Gamma glutamyl transferase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 13

**Description**  
Paraoxonase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 14

**Description**  
Superoxide dismutase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 15

**Description**  
Glutathione peroxidase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 16

**Description**  
Xanthine oxidase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 17

**Description**  
Glutathione reductase

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**  
blood analysis

## 18

**Description**  
Glutathione

**Timepoint**  
before intervention and 2 month after intervention

**Method of measurement**

blood analysis

## 19

### Description

MDA

### Timepoint

before intervention and 2 month after intervention

### Method of measurement

blood analysis

## Intervention groups

### 1

#### Description

Intervention group: Cumin extract, 15 mg/kg/day, oral, during 60days

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Rezvin, 10mg/kg/day, oral, during 60 days

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: VitC, 500 mg/day, oral, during 60 days

#### Category

Treatment - Drugs

### 4

#### Description

control group: Placebo, one Capsule per day, oral, during 60 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahrekord University of Medical Science

##### Full name of responsible person

Mohammad Hosein Gharib

##### Street address

Shahrekord University of Medical Science, Rahmatieh, Shahrekord

##### City

Shahrekord

### 2

#### Recruitment center

##### Name of recruitment center

Diabetic polyclinic

##### Full name of responsible person

Mohammad Mirzaei

##### Street address

Diabetic polyclinic, Chahar bagh bala, Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Shahrekord University of Medical Science

##### Full name of responsible person

Keyhan Ghatreh

##### Street address

Vice chancellor for research, Shahrekord University of Medical Science, Rahmatieh, Shahrekord

##### City

Shahrekord

#### Grant name

#### Grant code / Reference number

1393-01-87-2199

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

Yes

#### Title of funding source

Vice chancellor for research of Shahrekord 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

Shahrekord University of Medical Science

##### Full name of responsible person

Mohammad Hosein Gharib

##### Position

Msc student

##### Other areas of specialty/work

##### Street address

Shahrekord University of Medical Science, Rahmatieh, Shahrekord

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
keyhan Ghatreh  
**Position**  
Doctor of Biochemistry  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahrekord University of Medical Science  
**Full name of responsible person**  
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**Position**  
Msc student  
**Other areas of specialty/work**  
**Street address**  
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**City**  
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**Fax**  
**Email**  
mohogharib@skums.ac.ir  
**Web page address**

## 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*