

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of Resveratrol on some biochemical and hormonal factors in university staff

#### Protocol summary

##### Study aim

The effect of Resveratrol on some biochemical and hormonal factors in university staff

##### Design

Phase 3 clinical trial with control group, double-blind, randomized with Randomizer software with a sample size of 80 people

##### Settings and conduct

This study is a double-blind randomized clinical trial that will be performed at Qazvin University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Entry conditions: People between 18 to 50 years old  
Complete consent of individuals to participate in the study  
Having a BMI of 25 to 30 kg/m<sup>2</sup>  
No entry conditions: People having any allergies to the drug  
People with diabetes  
People with a history of high fat under treatment  
People taking vitamins and supplements  
People taking herbal medicines  
Patients with a history of inflammatory disease being treated  
People with known liver and kidney disease  
People with known lipid disease  
People treated with corticosteroids, aspirin and anti-lipids and hormonal drugs, hyperthyroidism and hypothyroidism  
People on drug treatment related to metabolic syndrome

##### Intervention groups

Group 1: People taking resveratrol  
Group 2: Control group with placebo

##### Main outcome variables

Measurement of body fat, Follicle-stimulating hormone, Dehydroepiandrosterone, Luteinizing hormone, fasting Insulin, Anti Mullerian hormone, Insulin-like growth factor 1, Interleukin 6, Self-monitoring of blood glucose, Testosterone, White Blood Cell, Lymphocyte, Neutrophil, Platelet, Body mass index, High-Sensitivity C-Reactive Protein, low-density lipoprotein, high density lipoprotein, triglycerides, Total antioxidant, Fasting Blood Sugar, Homeostatic Model Assessment for Insulin Resistance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200408046987N4**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **prospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

##### Registration date

2022-01-27, 1400/11/07

##### Registrant information

##### Name

Nematollah Gheibi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3332 8212

##### Email address

ngheibi@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-04, 1400/11/15

##### Expected recruitment end date

2022-03-06, 1400/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The effect of Resveratrol on some biochemical and hormonal factors in university staff |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Public title</b>                                                                    | The effect of Resveratrol on some biochemical and hormonal factors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Purpose</b>                                                                         | Health service research                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Inclusion/Exclusion criteria</b>                                                    | <p><b>Inclusion criteria:</b><br/>People between 18 to 50 years old Complete consent of individuals to participate in the study Having a BMI of 25 to 30 kg/m<sup>2</sup></p> <p><b>Exclusion criteria:</b><br/>People having any allergies to the drug People with diabetes People with a history of high fat under treatment People taking vitamins and supplements People taking herbal medicines Patients with a history of inflammatory disease being treated People with known liver and kidney disease People with known lipid disease People treated with corticosteroids, aspirin and anti-lipids and hormonal drugs, hyperthyroidism and hypothyroidism People on drug treatment related to metabolic syndrome</p> |
| <b>Age</b>                                                                             | From <b>18 years</b> old to <b>50 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Gender</b>                                                                          | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Phase</b>                                                                           | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Groups that have been masked</b>                                                    | <ul style="list-style-type: none"> <li>• Participant</li> <li>• Investigator</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sample size</b>                                                                     | Target sample size: <b>80</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Randomization (investigator's opinion)</b>                                          | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Randomization description</b>                                                       | In this study, a simple randomization method is used and a list of random numbers is created with Randomizer software. The software randomly divides this list from 1 to 80 between the control and intervention groups. Depending on the order of patients' referrals, they are given a number from 1 to 80 from the list of random numbers, and based on the list created by the software, which assigns each number to one of the two control and intervention groups, people enter the intervention or control group. be.                                                                                                                                                                                                |
| <b>Blinding (investigator's opinion)</b>                                               | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Blinding description</b>                                                            | Participants will be given medication or placebo after signing the consent form. The therapist and outcome assessor will not know the type of treatment, and the data analyzer will only know the group numbers.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Placebo</b>                                                                         | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Assignment</b>                                                                      | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Other design features</b>                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Qazvin university of medical sciences

##### Street address

Bahonar Blvd

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3419915315

#### Approval date

2021-03-15, 1399/12/25

#### Ethics committee reference number

IR.QUMS.REC.1399.569

## Health conditions studied

### 1

#### Description of health condition studied

Metabolic syndrome

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Measurement of fasting Insulin

#### Timepoint

Before starting intervention and one month after intervention

#### Method of measurement

At the beginning and end of the study, it will be measured by Snible kit

### 2

#### Description

Measuring the mass of fat accumulated in the body

#### Timepoint

Before starting intervention and one month after intervention

#### Method of measurement

At the beginning and end of the study, the amount of accumulated fat will be measured with a digital scale

### 3

#### Description

Measurement of Follicle Stimulating Hormone

#### Timepoint

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by Snible kit

**4**

**Description**

Measurement of Luteinizing hormone

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by Snible kit

**5**

**Description**

Measurement of Dehydroepiandrosterone

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by Snible kit

**6**

**Description**

Measurement of Anti Mullerian hormone

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by kit

**7**

**Description**

Measurement of Insulin-like growth factor 1

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by kit

**8**

**Description**

Measurement of Interleukin 6

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by kit

**9**

**Description**

Measurement of Self-monitoring of blood glucose

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by kit

**10**

**Description**

Measurement of Testosterone

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by kit

**11**

**Description**

Measurement of White Blood Cell

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by cell counter

**12**

**Description**

Measurement of Lymphocyte

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by cell counter

**13**

**Description**

Measurement of Neutrophil

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be measured by cell counter

**14**

**Description**

Measurement of Platelet

**Timepoint**

Before starting intervention and one month after intervention

**Method of measurement**

At the beginning and end of the study, it will be

measured by cell counter

## **15**

### **Description**

Measurement of Body Mass Index

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

Weight (in kilograms) Divided by Height (in meters to the power of 2)

## **16**

### **Description**

Measurement of High-Sensitivity C-Reactive Protein

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by Rosh kit (in mg/dL)

## **17**

### **Description**

Measurement of Low-density lipoprotein

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **18**

### **Description**

Measurement of High-density lipoprotein

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **19**

### **Description**

Measurement of Triglyceride

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **20**

### **Description**

Measurement of Total Antioxidant

### **Timepoint**

Before starting intervention and one month after

intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **21**

### **Description**

Measurement of Fasting Blood Sugar

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **22**

### **Description**

Measurement of Homeostatic Model Assessment for Insulin Resistance

### **Timepoint**

Before starting intervention and one month after intervention

### **Method of measurement**

At the beginning and end of the study, it will be measured by kit

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: People in this group take Resveratrol (An active compound of acetylene phytoalexin) capsule supplements once a day before meals for a month.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: People in this group take one 1000 mg capsule containing wheat flour instead of Resveratrol every day for a month before a meal.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Qazvin university of medical sciences

##### **Full name of responsible person**

Dr. Nematollah Gheibi

##### **Street address**

Bahonar Blvd

**City**  
Qazvin  
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3419915315  
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+98 28 3332 8212  
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ngheibi@qums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr. Nematollah Gheibi  
**Street address**  
Bahonar Blvd  
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**Province**  
Qazvin  
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**Email**  
ngheibi@qums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Qazvin 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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr. Nematollah Gheibi  
**Position**  
University professor  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
Medical Physics  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Position**  
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**Other areas of specialty/work**  
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Qazvin

**Postal code**  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to

make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Undecided - It is not yet known if there will be a plan to make this available  
**Data Dictionary**  
Not applicable