

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of resveratrol on hyperlipidemia caused by anti-retroviral drug therapy in HIV patients

#### Protocol summary

##### Study aim

1. Determination of the effect of resveratrol on blood lipid profile 2. Determination of the effect of resveratrol on liver function tests 3. Determination of the effect of resveratrol on lipid peroxidation in plasma samples

##### Design

Before and after a 1-month course of resveratrol and placebo treatment, 15 ml of intravenous blood is taken from each patient after 12 hours of fasting. Blood samples are sent to the laboratory for the following tests: 1- Blood biochemical tests including lipid profile 2- Liver function tests including ALT and AST 3- Level of fat peroxidation 4- Total plasma antioxidant capacity

##### Settings and conduct

The clinical trial will be conducted at the Behavioral Sciences Clinic in collaboration with the AIDS Research Center. Among the HIV patients who come to this clinic, The total number of people living with HIV infection is 200, of which 40 are for the resveratrol group (250 mg per day) and 40 for the placebo group (250 mg starch).

##### Participants/Inclusion and exclusion criteria

Exclusion criteria: History of disorders in lipid profile before treatment with antiretroviral drugs, history of cardiovascular and/or cerebral disease, Cushing's syndrome, hypothyroidism, type 1 or type 2 diabetes, renal failure, previous or current treatment with drugs for the treatment of hyperlipidemia and hypertension, estrogens, and current drug and/or alcohol abuse.

##### Intervention groups

administration of resveratrol with other drugs

##### Main outcome variables

Cholesterol-Triglyceride - HDL -LDL- ALT- AST- Carbonyl groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180114038356N2**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

##### Registration date

2020-05-23, 1399/03/03

##### Registrant information

###### Name

Somayyeh Karami-Mohajeri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3132 5001

###### Email address

somayyehkarami@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of resveratrol on hyperlipidemia caused by anti-retroviral drug therapy in HIV patients

##### Public title

The effect of resveratrol on anti-HIV hyperglycemia

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Sustainable treatment with triple-drug regimen for at least 12 months. LDL > 130 mg / dL or triglyceride 200-500 mg / dL and HDL > 160 mg / dL, with no regular diet and exercise for at least 3 months

### Exclusion criteria:

Exclusion criteria were: history of pre-antiretroviral lipid disorders, history of cardiovascular and / or cerebral disease, Cushing's syndrome, hypothyroidism, type 1 or type 2 diabetes, renal failure, previous or current treatment with reduced risk factors. Lipid donors, antihypertensive drugs or estrogens, current drug and / or alcohol abuse.

## Age

From 18 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The drugs were identified by the code provided to the treating physician. The test results were then presented to the statistician and then the groups were analyzed based on the code.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kerman University of Medical Sciences

##### Street address

Kerman University of Pharmacy, School of Pharmacy, Third Floor, Nursing Home, Dr. Karma Mohajeri

##### City

kerman

##### Province

Kerman

##### Postal code

7618835559

##### Approval date

2019-07-30, 1398/05/08

##### Ethics committee reference number

IR.KMU.REC.1398.200

## Health conditions studied

### 1

#### Description of health condition studied

The effect of resveratrol on reducing cholesterol in people with HIV

#### ICD-10 code

B20-B24

#### ICD-10 code description

Human immunodeficiency virus [HIV] disease

## Primary outcomes

### 1

#### Description

Triglyceride

#### Timepoint

1 month

#### Method of measurement

Each patient received 15 ml fasting venous blood before and after 1 month of treatment with resveratrol and placebo and sent to the laboratory.

### 2

#### Description

Cholesterol

#### Timepoint

1MONTH

#### Method of measurement

Each patient received 15 ml fasting venous blood before and after 1 month of treatment with resveratrol and placebo and sent to the laboratory.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group

#### Category

Treatment - Drugs

### 2

#### Description

Control group

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Behavioral Sciences Clinic affiliated to Kerman  
University of Medical Sciences

**Full name of responsible person**

Dr. Somayeh Karami Mohajeri

**Street address**

Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5239

**Email**

somayyekarami@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Pardakhty

**Street address**

Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

kerman

**Province**

Kerman

**Postal code**

76188355559

**Phone**

+98 34 3132 5239

**Email**

somayyekarami@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kermanshah 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Somayeh Karami Mohajeri

**Position**

University professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

pharmacology

**Street address**

Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

kerman

**Province**

Kerman

**Postal code**

76188355559

**Phone**

009831325239

**Email**

somayyekarami@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

University professor

**Position**

University professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

pharmacology

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kerman

**Province**

Kerman

**Postal code**

76188355559

**Phone**

009831325239

**Email**

somayyekarami@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Somayeh Karami Mohajeri

**Position**

University professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

pharmacology

**Street address**

Seven Gardens of Alavi School of Pharmacy

**City**

kerman

**Province**

Kerman

**Postal code**

76188355559

**Phone**

009831325239

**Email**

somayyekarami@gmail.com

## 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**

Undecided - It is not yet known if there will be a plan to make this available