

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhty

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Kerman University of Medical Sciences, Medical
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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

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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

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