Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 University Campus,Haft-Bagh Highway, Kerman, Iran

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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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Person responsible for updating data

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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