Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Investigation the effects of palmitate and cichoric acid on inflammation pathway in PBMCs of type2 diabetic patient and control group

Protocol summary

Summary

In this study, the effects of palmitate and chicoric acid on the expression of SIRT1 and IL-6 genes, and the levels of p-AMPK and IL-6 proteins in PBMCs of type 2 diabetic patients and healthy individuals will be investigated. This study is on 40 people (20 people with type 2 diabetes and 20 healthy people). People with type 2 diabetes have fasting blood glucose levels equal to or greater than 126 mg/dL; 2 hours of glucose equal to or greater than 200 mg/dl; HbA1c equal to or greater than 6.5% and are approved by the diagnosis of the endocrinologist. The control group should have a fasting blood sugar lower than 100 mg/dl. Exclude criteria include the use of drugs such as antihypertensive drugs; other acute and chronic inflammatory diseases; pregnancy and.... Blood samples were taken from participants in this study, then the plasma and their PBMC cells are isolated. PBMCs are treated with palmitate and chicoric acid for 24 hours. Then, the effects of palmitate and chicoric acid alone and along with on the expression of SIRT1 and IL-6 genes, and the level of p-AMPK and IL-6 proteins in PBMC cells are investigated. As a result, the effect of chicoric acid on insulin signaling pathway and improvement of status in type 2 diabetics is investigated

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071535085N1**
Registration date: **2017-08-02, 1396/05/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-02, 1396/05/11

Registrant information

Name
Nasrin Ziamajidi
Name of organization / entity
Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effects of palmitate and cichoric acid on inflammation pathway in PBMCs of type2 diabetic patient and control group

Public title

The effects of palmitate and chicoric acid on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: FBS greater than 126 mg/dL; 2 hours blood glucose greater than 200 mg/dl; HbA1C greater than 6.5%; The control group should have a fasting blood glucose less than 100 mg/dl. Exclusion criteria: Use of

medications such as antihypertensive drugs (such as beta-blockers), anti-diabetic drugs, estrogen supplements, thyroxine, diuretics and hypolipemic drugs; Other chronic and acute inflammatory diseases such as chronic kidney disease, cardiovascular disease, hypertension and ...; Infectious diseases, cancer, allergies; Other Endocrine Disorders (Except Type 2 Diabetes); Pregnancy; Smoking

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, opposite the People's Park, Hamadan

City
Hamadan

Postal code
6517838678

Approval date
2017-07-08, 1396/04/17

Ethics committee reference number
IR.UMSHA.REC.1396.291

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
SIRT1

Timepoint
One day after the intervention, Two day after the intervention

Method of measurement
Gene expression of SIRT1 using Ct of gene

2

Description
IL-6

Timepoint
One day after the intervention, Two day after the intervention

Method of measurement
Gene expression of IL-6 using Ct of gene

3

Description
p-AMPK

Timepoint
One day after the intervention, Two day after the intervention

Method of measurement
concentration of p-AMPK using western blotting

Secondary outcomes

empty

Intervention groups

1

Description
Group (4) treatments with palmitate (500 µM) plus chicoric acid (50 µM), the cells of this group are treated with palmitate at a concentration of 500 µM for 24 hours. Then, they are treated with chicoric acid at a concentration of 50 µM for 24 hours.

Category
Treatment - Drugs

2

Description
Separation of the cells is according to the ficole protocol. In the next step, cell pellets are suspended in the 2 cc culture medium and cell count evaluates using trypan blue. The cells are cultured in the plates in the culture medium. In this environment, a fetal bovine serum 10% and penicillin/streptomycin 1% is added. The cells are kept in a 5% carbon dioxide incubator at 37 °C for 24 hours to keep the cells in stable condition. Then, the cells

are divided into four groups: Group (1) untreated cells (control group). The control group contains cells that are treated with a bovine serum albumin 1%

Category

Treatment - Drugs

3

Description

Group (3) treatment with chicoric acid at a concentration of 50 µM. The chicoric acid was dissolved in dimethyl sulfoxide and then reached the desired volume using the culture medium. The cells of this group were treated with chicoric acid at a concentration of 50 µM for 24 hours.

Category

Treatment - Drugs

4

Description

Group (2) treatment with palmitate with a concentration of 500 µM. Sodium palmitate was dissolved in 50% ethanol at 55 °C. Then, using a culture medium containing bovine serum albumin 1% reached the desired volume and was sterilized before use. The cells of this group were treated with palmitate at a concentration of 500 µM for 24 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Nasrin Ziamajidi

Street address

Department of Clinical Biochemistry, Faculty of Medicine, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Department of Clinical Biochemistry, Faculty of Medicine, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan University of Medical Sciences

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

Hamadan University of Medical Sciences

Full name of responsible person

Nasrin Ziamajidi

Position

Ph.D

Other areas of specialty/work

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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