Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of ascorbic acid on AGEs, AOPP ,FRAP, hsp70,hsCRP, ox- LDL ,leptinand HOMA in patients with type 2diabetes

Protocol summary

Study aim

The aim of this study is to investigate the effects of vitamin c supplementation, as an antioxidant agent, on advanced glycation end products(AGEs), Advanced Oxidation Protein Products(AOPP) and Ferritin Reducing Ability of Plasma (FRAP) , heat shock protein 70 (hsp70), CRP, ox-LDL(oxidized LDL) , leptin and insulin resistance in patients with type 2 diabetes mellitus.

Design

Randomized double blind clinical trial including 70 patients with type2 diabetes.

Settings and conduct

This is a randomized double blind clinical trial study on 70 patients with type2 diabetes. After evaluation of inclusion and exclusion criteria, patients will be randomly divided into 2 groups including vitamin C and placebo group. Vitamin C and placebo will prescribe to each group for 2 months. Before treatment and after 2 month blood samples will be taken and stored at -70 c. All samples will be analyzed by standard methods. This study will be conducted at diabetes clinic of the vali-asr hospital which is affiliated with Tehran University of Medical Sciences,Tehran,Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria; type2 diabetes, age more than 30 year. Exclusion criteria ; type1 diabetes, pregnancy, current vitamins use, renal failure, history of heart failure, smoking, liver failure, malignancy, hypersensitivity to vitamin C, acute inflammation and infection.

Intervention groups

In this study intervention is prescription of vitamin c and it's placebo randomly in 2 groups.

Main outcome variables

Advanced glycation end products(AGEs), Advanced Oxidation Protein Products(AOPP), Ferritin Reducing Ability of Plasma (FRAP), heat shock protein 70 (hsp70), CRP, ox-LDL(oxidized LDL), leptin and insulin resistance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160811029306N1**
Registration date: **2018-10-06, 1397/07/14**
Registration timing: **prospective**

Last update: **2018-10-06, 1397/07/14**
Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

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Manouchehr Nakhjavani
Name of organization / entity
Tehran University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of ascorbic acid on AGEs, AOPP ,FRAP, hsp70,hsCRP, ox- LDL ,leptinand HOMA in patients with type 2diabetes

Public title
Vitamin c in Diabetes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
type2 diabetes older than 30
Exclusion criteria:
type1 diabetes pregnancy renal failure history ofheart failure liver failure malignancy smoking acute inflammation infection hypersensitivity to vitamin C current vitamins use
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a randomized double blind clinical trial study.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind study.Both participants and investigator are blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of National Institute for Medical Research Development
Street address
No 21, Besat Ave, West Fatemi Blvd,Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۶۹۳۱۱۱
Approval date
2018-07-01, 1397/04/10
Ethics committee reference number
IR.NIMAD.REC.1397.123

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Advancedglycation end products(AGEs)
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
AGEs will be measured by the spectrophotometric method in endocrine laboratory of vali-asr hospital.

2

Description
AOPP
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
AOPP concentrations will be measured by spectrophotometric methods

3

Description
FRAP
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
FRAP will be assessed by spectrophotometric method

4

Description
ox LDL
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
OX LDL will be measured using commercially available

sandwich enzymelinked immunosorbent assay

5

Description
HSP70
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
HSP70 will be measured using a quantitative sandwich ELISA immunoassay

6

Description
Hs-CRP
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
Hs-CRP will be assessed by a two-site enzyme-linked immunosorbent assay

7

Description
Leptin
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
Leptin leptin concentration will be measured by an ELISA assay

8

Description
Insulin
Timepoint
Blood samples will be taken before treatment and after 2 month of treatment.
Method of measurement
Fasting insulin was measured using radioimmunoassay techniques

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral Vitamin c supplement
Category
Prevention

2

Description
Control group: placebo
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes clinic of Vali-asr Hospital
Full name of responsible person
Manouchehr Nakhjavani
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No 20, Keshavarz Blvd,Tehran,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Institute for Medical Research Development
Full name of responsible person
Reza Malekzadeh
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No 21, Besat Ave, West Fatemi Blvd,Tehran,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
National Institute for Medical Research Development
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
Tehran University of Medical Sciences
Full name of responsible person
Manouchehr Nakhjavani
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and metabolism
Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Given the confidentiality of the information of the patients participating in this study, I do not intend to publish the participant's data file.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available