Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of non-surgical periodontal therapy with Cichorium Intybus L. Leaf Extract on antioxidant status, inflammation and blood lipid status of patients with periodontal disease

Protocol summary

Summary

Objective: To determine the effect of non-surgical periodontal therapy with Cichorium Intybus L. Leaf Extract on antioxidant status, inflammation and blood lipid status of patients with periodontal disease. This study is a randomized, double-blind, controlled (an intervention group and a control group (placebo)), two central and Phase 3 of clinical trial that will be done on 40 patients with periodontal disease referred to dental clinic of Ahvaz University of Medical Sciences. Inclusion criteria: age over 30 years; having periodontal disease (PPD more than 4 millimeter) in at least one site in the three quarters of the mouth); BMI more than 18.5 Kilogram/ square meter. Exclusion criteria: lack of cooperation; pregnancy and lactation; smoking; use of dietary supplements and antioxidant; Consumption of anti cariogenic gum; Consumption of drugs that suppress the immune system; changes in diet pattern and hyperlipidemia. Forty periodental patient were randomly divided into two groups by using a table of random numbers;intervention and control group; after the Non surgical periodontal therapy. Individuals in the intervention group, receive two one-gram capsules daily containing total of 2 grams of Cichorium Intybus L. Leaf extract in the morning and evening for 8 weeks and control group receive one-gram placebo capsules containing 2 grams of wheat flour. The primary expected outcomes are changes in serum levels of Interleukin-6, hs-CRP, malondialdehyde (MDA), uric acid, triglycerides, cholesterol, High Density Lipoprotein(HDL) and also the change in the total antioxidant capacity of the blood compared with baseline in the intervention group and the control before and after two months after intervention.

General information

Acronym

Cichorium Intybus L. Leaf Extract and periodontal

IRCT registration information

IRCT registration number: **IRCT2015112825274N1**
Registration date: **2016-01-14, 1394/10/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-14, 1394/10/24

Registrant information

Name

Ahmad Zare Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arvand International Division of Ahvaz Jundishapur University of Medical Sciences/Pharmaceutical Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of non-surgical periodontal therapy with Cichorium Intybus L. Leaf Extract on antioxidant status, inflammation and blood lipid status of patients with periodontal disease

Public title
Effects of Cichorium Intybus L. Leaf Extract on improvement of the clinical status of patients with periodontal
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age over 30 years; having periodontal disease (PPD more than 4 millimeter) in at least one site in the three quarters of the mouth); BMI more than 18.5 Kilogram/ square meter. Exclusion criteria: lack of cooperation; pregnancy and lactation; smoking; use of dietary supplements and antioxidant; Consumption of anti cariogenic gum; Consumption of drugs that suppress the immune system; changes in diet pattern and hyperlipidemia.
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Patients randomly divided into two groups by using a table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Faculty of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
City
Ahvaz
Postal code
Approval date
2014-04-14, 1393/01/25
Ethics committee reference number
Ajums. REC.1392,177

Health conditions studied

1

Description of health condition studied
periodental
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
Interleukin-6
Timepoint
Before and two months after intervention
Method of measurement
ELISA

2

Description
hs-CRP
Timepoint
Before and two months after intervention
Method of measurement
ELISA

3

Description
malon de aldehid (MDA)
Timepoint
Before and two months after intervention
Method of measurement
chemical method (Kit)

4

Description
Blood uric acid
Timepoint
Before and two months after intervention
Method of measurement
chemical method

5

Description
Triglycerides
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

6

Description
cholesterol
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

7

Description
HDL-cholesterol
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

8

Description
Total antioxidant capacity of blood
Timepoint
Before and two months after intervention
Method of measurement
Enzymatic

Secondary outcomes

1

Description
weight
Timepoint
Before and two months after intervention
Method of measurement
scale

2

Description
height
Timepoint
Before and two months after intervention
Method of measurement
Stadiometer

3

Description
Energy intake
Timepoint
Before and two months after intervention
Method of measurement
recall

4

Description
Carbohydrate intake
Timepoint
Before and two months after intervention
Method of measurement
recall

5

Description
Protein intake
Timepoint
Before and two months after intervention
Method of measurement
recall

6

Description
fat intake
Timepoint
Before and two months after intervention
Method of measurement
recall

7

Description
saturated Fat
Timepoint
Before and two months after intervention
Method of measurement
recall

8

Description
Vitamin A
Timepoint
Before and two months after intervention
Method of measurement
recall

9

Description
Vitamin C
Timepoint
Before and two months after intervention
Method of measurement
recall

10

Description
vitamin E
Timepoint
Before and two months after intervention
Method of measurement
recall

11

Description
betacaroten
Timepoint
Before and two months after intervention
Method of measurement
recall

Intervention groups

1

Description
Intervention group1: Consumption of two one-gram capsules daily containing total of 2 grams of Cichorium Intybus L. Leaf extract (By using fresh leaf of Cichorium Intybus L from Kandovan city, located in Azerbaijan, extracts and capsules prepared by the Center for Pharmaceutical Research, Tabriz University of Medical Sciences), in the morning and evening for 8 weeks
Category
Other

2

Description
Control group: Consumption of two one-gram capsules daily containing 2 grams of wheat flour (capsules prepared by the Center for Pharmaceutical Research, Tabriz University of Medical Sciences), in the morning and evening for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics clinic, Dental School, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Doctor Yousefi manesh
Street address
Dental School, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Arvand International Division of Ahvaz Jundishapur University of Med
Full name of responsible person
Dr Bahram Abdali
Street address
Education section, Arvand International Division of Ahvaz Jundishapur University of Medical Sciences , Opposite the international airport of Abadan, Parastar Square, Abadan, Khuzestan,Iran Abadan
City
Abadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Arvand International Division of Ahvaz Jundishapur University of Med
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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Position
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Other areas of specialty/work
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Other areas of specialty/work

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Person responsible for updating data

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Web page address

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