

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 periodontal 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)

Phone

+98 61 3373 8319

Email address

zarejavid-a@ajums.ac.ir

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.

AgeFrom **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**

periodontal

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 aldehyd (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

Ahmad Zare Javid

Position

PhD of Nutrition sciences/Assistant Professor

Other areas of specialty/work

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Email**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

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ahmad ZareJavid

Position

PhD of Nutrition sciences/Assistant Professor

Other areas of specialty/work**Street address**

School of Paramedicine, Ahvaz Jundishapur University