

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of Ginger supplement in Adjunct with Non-surgical periodontal Therapy on Periodontal status, Glycemic Control, lipid profile, Antioxidant status and some inflammatory markers in type 2 Diabetes Patients with Periodontitis

Protocol summary

Summary

The purpose of this study is to investigate the Effect of Ginger supplement in Adjunct with Non-surgical Periodontal Therapy on Periodontal status, Glycemic Control, lipid profile, Antioxidant status and some inflammatory markers in type 2 Diabetes Patients with Periodontitis. In this double-blind, single center clinical trial study, 46 diabetic patients with chronic periodontitis are selected and randomly divided into two intervention (n=23) and control (n=23) groups. Randomization will be done using sealed envelope method. The intervention group will receive four Ginger tablets(500 mg produced by Dineh Company, Iran) for 60 days, equal to 2 grams per day (1g before lunch, 1g before dinner). The control group will receive four 500 mg placebo tablets (containing flour pease) for 60 days. Non-surgical periodontal therapy will be performed for all patients during this study. Some demographic data including Age, Sex, Anthropometric indices such as: Weight, Height, BMI, Waist and Hip circumferences; Biochemical indices including: Fasting blood glucose, HbA1C, lipid profile, Antioxidant status(MDA , TAC) and some inflammatory markers(TNF- α , HS-CRP) and Periodontal indices (Bleeding index, Pocket depth, Plaque index and Clinical attachment level), Physical activity and 3-days 24-hour recall are evaluated pre and post intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030432874N1**

Registration date: **2017-04-04, 1396/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

Name

Hasan Gholinezhad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61336754360

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-06-04, 1396/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ginger supplement in Adjunct with Non-surgical periodontal Therapy on Periodontal status, Glycemic Control, lipid profile, Antioxidant status and some inflammatory markers in type 2 Diabetes Patients with

Periodontitis

Public title

The effect of Ginger supplementation in the treatment of type 2 Diabetic patients with Periodontitis.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Males and females aged 30 – 60 year; type 2 Diabetic patients who have been suffering from the disease for at least 5 years and have chronic periodontal disease; BMI ≥ 18.5 and $< 30\text{kg/m}^2$.
Exclusion criteria: Diabetic patients being under insulin therapy; Pregnancy; Breast feeding ; History of Periodontal treatment

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur
University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan, Iran

City

Ahvaz

Postal code

61357-15794

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.AJUMS.REC.1395.806

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent Diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

2

Description

HbA1C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

3

Description

LDL.C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

4

Description

HDL.C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

5

Description

Triglyceride

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

6

Description

Total cholestrol

Timepoint

Before and after the intervention
Method of measurement
Using enzymatic kit method

7

Description
TNF- α
Timepoint
Before and after the intervention
Method of measurement
ELISA

8

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

9

Description
MDA
Timepoint
Before and after the intervention
Method of measurement
ELISA

10

Description
TAC
Timepoint
Before and after the intervention
Method of measurement
ELISA

11

Description
Bleeding during probe
Timepoint
Before and after the intervention
Method of measurement
Evaluation of bleeding

12

Description
Plaque index
Timepoint
Before and after the intervention
Method of measurement
Plaque is on the tooth surface

13

Description
Clinical attachment level
Timepoint
Before and after the intervention

Method of measurement
Depth study of cement and enamel plaque periodontal

14

Description
Pocket dept
Timepoint
Before and after the intervention
Method of measurement
The probing depth is measured by the probe.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group receives four 500 mg Ginger tablets per day(1g before lunch, 1g before dinner) for 60 days.
Category
Other

2

Description
The Control group receives four 500 mg placebo tablets (containing flour pease) per day (1g before lunch, 1g before dinner), for 60 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Golestan Hospital
Full name of responsible person
hasan gholinezhad
Street address
Golestan treatment training center, Golestan street, Ahvaz, Khosetan, Iran
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan, Iran

City

Ahvaz

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 Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hasan Gholinezhad

Position

MSc student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Ahmad Zarejavid

Position

Professor of Ahvaz Jundishapur University of Medical
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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