

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of ginger supplementation in adjunct with non-surgical periodontal therapy on periodontal status, serum levels of interleukin 6 and some serum antioxidant markers in type 2 diabetic patients with chronic periodontitis

Protocol summary

Study aim

The aim of this study is to evaluate the effects of ginger supplementation in adjunct with non- surgical periodontal therapy on periodontal status, interleukin 6 and some antioxidant parameters in T2DM patients with chronic periodontitis.

Design

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.

Settings and conduct

In this double-blinded clinical trial, 96 type 2 diabetes mellitus patients with some symptoms of periodontal disease are recruited from endocrinology and metabolism clinics of Golestan Hospital of Ahvaz Jundishapur University of Medical Science, Iran. Subjects are referred to Dental Clinic for further diagnosis to confirm periodontal disease. coding done by a third person of health care who does not know anything about the research and the researchers and patients does not know about the contents of the packets.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Males and females aged 30 - 60 y; type 2 diabetic patients who have been suffering from the disease for at least 5 years; 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; thyroid disorders.

Intervention groups

In this double-blind clinical trial, 46 diabetic patients with chronic periodontitis are selected and randomly divided into two intervention (n=23) and control (n=23) groups. The intervention group receives four 500 mg ginger

tablets per day (1g before lunch, 1g before dinner) for 60 days. Also, the control group receives four 500 mg placebo tablets (containing chickpea flour) per day (1g before lunch, 1g before dinner), for 60 days. The placebo and ginger tablets are produced by Dineh Company, Iran.

Main outcome variables

The serum levels of IL-6; Activity of antioxidant enzymes (SOD; CAT; GSHPx); Periodontal indices including (Bleeding index; Pocket depth; Plaque index and Clinical attachment level).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170304032874N2**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **retrospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Hasan Gholinezhad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2018-04-09, 1397/01/20

Expected recruitment end date

2018-06-10, 1397/03/20

Actual recruitment start date

2017-04-03, 1396/01/14

Actual recruitment end date

2017-06-04, 1396/03/14

Trial completion date

empty

Scientific title

Effect of ginger supplementation in adjunct with non-surgical periodontal therapy on periodontal status, serum levels of interleukin 6 and some serum antioxidant markers in type 2 diabetic patients with chronic periodontitis

Public title

Effect of ginger supplementation in treatment of type 2 diabetic patients with chronic 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 type 2 Diabetic patients who 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 Thyroid disorders

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

46 subjects are randomly divided into two intervention (n=23) and control (n=23) groups by a permuted block procedure

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, coding will be done by a third person of

health care who do not know anything about this research, and researchers and patients will not be aware of the contents of the packets.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

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

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.AJUMS.REC.1396.925

Health conditions studied**1****Description of health condition studied**

type 2 diabetic patients with chronic periodontitis disorder.

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

IL-6

Timepoint

Before and after the intervention

Method of measurement

Elisa

2**Description**

SOD

Timepoint

Before and after the intervention

Method of measurement

Elisa

3**Description**

GSHPx

Timepoint

Before and after the intervention

Method of measurement

Elisa

4**Description**

CAT

Timepoint

Before and after the intervention

Method of measurement

Elisa

5**Description**

Bleeding during probe

Timepoint

Before and after the intervention

Method of measurement

Evaluation of bleeding

6**Description**

Plaque index

Timepoint

Before and after the intervention

Method of measurement

Plaque is on the tooth surface

7**Description**

Clinical attachment level

Timepoint

Before and after the intervention

Method of measurement

Depth study of cement and enamel plaque periodontal

8**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. the ginger tablets were produced by Dineh Company, Iran

Category

Other

2**Description**

Control group: The Control group receives four 500 mg placebo tablets (containing flour pease) per day (1g before lunch, 1g before dinner), for 60 days. the placebo tablets are produced by Dineh Company, Iran.

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

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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

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Hasan Gholinezhad

Position

MSc student of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ahmad Zarejavid

Position

Professor of Ahvaz Jundishapur University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available