

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of a probiotic supplementation versus no treatment on level of salivary TNF- α in patients with type 2 diabetes: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of a probiotic supplementation versus no treatment on level of salivary TNF- α in patients with type 2 diabetes. Design: a randomized clinical trial. Setting and conduct: The eligible patients who will refer to the School of Dentistry during the study period will be enrolled into the trial. Inclusion criteria: (a) having type 2 diabetes; (b) body mass index equal to or greater than 25. Exclusion criteria: (a) using insulin, corticosteroids, immunosuppressive drugs, or non-steroidal anti-inflammatory drugs; (b) smoking; (c) thyroid dysfunction; (d) cardiovascular diseases or renal failure; (e) pregnancy or breastfeeding; (f) using any kind of probiotic products in the past two months. Intervention group: Routine treatment plus Familact capsule 500 mg one a day for 8 weeks Control group: Routine treatment only. Primary outcome: Measuring the level of TNF- α using Bendcrmedsystem kit in fourth and eighth weeks after treatment. Secondary outcome: Nothing. Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: without blinding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603029014N93**
Registration date: **2016-04-03, 1395/01/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a probiotic supplementation versus no treatment on level of salivary TNF- α in patients with type 2 diabetes: a randomized clinical trial

Public title

The effect of a probiotic supplementation versus no treatment on level of salivary TNF- α in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) having type 2 diabetes; (b) body

mass index equal to or greater than 25. Exclusion criteria: (a) using insulin, corticosteroids, immunosuppressive drugs, or non-steroidal anti-inflammatory drugs; (b) smoking; (c) thyroid dysfunction; (d) cardiovascular diseases or renal failure; (e) pregnancy or breastfeeding; (f) using any kind of probiotic products in the past two months.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups one at a time.

Blinding: without blinding.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-12-26, 1394/10/05

Ethics committee reference number

IR.UMSHA.REC.1394.404

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

Measuring the level of TNF- α

Timepoint

in fourth and eighth weeks after treatment

Method of measurement

using Bendcrmedsystem kit

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

Routine treatment plus Familact capsule 500 mg one a day for 8 weeks

Category

Treatment - Drugs

2

Description

Routine treatment only

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Maryam Mardani

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid fahmideh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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**

School of Dentistry

Full name of responsible person

Maryam Mardani

Position

Dentistry Student

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

School of Dentistry, Hamadan University of Medical
Sciences, Shahid fahmideh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3838 1086

Fax**Email**

maryammardani292@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Dentistry

Full name of responsible person

Dr Mohammad Vahedi

Position

Oral and Maxillofacial Specialist

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

School of Dentistry, Hamadan University of Medical
Sciences, Shahid fahmideh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3838 1086

Fax**Email**

vahedi_md@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

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