

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of melatonin supplement along with non surgical periodontal therapy on periodontal status, salivary melatonin, glycemic control, inflammatory markers and blood lipid profile in type 2 diabetic patients with chronic periodontitis

Protocol summary

Summary

The purpose of this study is to investigate the effect of melatonin supplement along with non-surgical periodontal therapy on periodontal status, salivary melatonin, glycemic control, inflammatory markers and blood lipid profile in type 2 diabetic patients with chronic periodontitis. In this double-blind, single center clinical trial 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 two 3 mg Melatonin tablets per day, one hour before bedtime, for 60 days. The control group will receive two 3 mg placebo tablets (containing cellulose, silicon dioxide and starch) one hour before bedtime, 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 circumference; biochemical indices including fasting blood glucose, HbA1C, lipid factors, inflammatory markers (IL-6 and hs-CRP), salivary melatonin; periodontal indices (bleeding index, pocket depth, plaque index and clinical attachment level), physical activity and 3-day 24-hour recall are evaluated pre and post intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011631993N1**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Hadi Bazyar

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 74 3333 1257

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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

2017-01-29, 1395/11/10

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin supplement along with non surgical periodontal therapy on periodontal status, salivary melatonin, glycemic control, inflammatory markers and blood lipid profile in type 2 diabetic patients

with chronic periodontitis

Public title

The effect of melatonin supplementation in the treatment of type 2 diabetic patients with chronic periodontitis disorder.

Purpose

Supportive

Inclusion/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 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

Sealed pocket

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 Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2017-01-17, 1395/10/28

Ethics committee reference number

IR.AJUMS.REC.1395.685

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

IL-6

Timepoint

Before and after the intervention

Method of measurement

ELISA

2

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

3

Description

hs-CRP

Timepoint

Before and after the intervention

Method of measurement

ELISA

4

Description

HbA1C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

5

Description

HDL.C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

6

Description

Triglyceride

Timepoint

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

7

Description

LDL.C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

8

Description

Total cholesterol

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

9

Description

Salivary malatonin

Timepoint

Before and after the intervention

Method of measurement

ELISA

10

Description

Bleeding during probe

Timepoint

Before and after the intervention

Method of measurement

Evaluation of bleeding

11

Description

Plaque index

Timepoint

Before and after the intervention

Method of measurement

Plaque is on the tooth surface

12

Description

Pocket dept

Timepoint

Before and after the intervention

Method of measurement

The probing depth is measured by the probe.

13

Description

Clinical attachment level

Timepoint

Before and after the intervention

Method of measurement

Depth study of cement and enamel plaque periodontal

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives two 3-mg Melatonin tablets per day, 1 hour before bedtime, for 60 days.

Category

Other

2

Description

The control group receives two 3-mg placebo tablets (containing cellulose, silicon dioxide and starch) per day, 1 hour before bedtime, for 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Golestan Hospital

Full name of responsible person

Street address

Ahvaz Jundishapur University of Medical Sciences,
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

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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

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

Hadi Bazyar

Position

Msc Student of Nutrition

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

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Full name of responsible person

Dr. Ahmad Zarejavid

Position

Professor of Ahvaz Jundishapur University of Medical
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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