Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Melatonin supplement with Non surgical periodontal therapy on periodontal status, some inflammatory markers and serum antioxidant status in type 2 diabetic patients with chronic periodontitis.

Protocol summary

Summary

The purpose of this study is to investigate Effect of Melatonin supplement with Non surgical periodontal therapy on periodontal status, some inflammatory markers and serum antioxidant status in type 2 diabetic patients with chronic periodontitis.In this double-blind, single center clinical trial 50 diabetic patients with chronic periodontitis are selected and randomly divided into two intervention (n=25) and control (n=25) 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 stud (Below and above the gum scaling). demographic data including age; sex; anthropometric indices such as weight, height, BMI, waist and hip circumference; some serum inflammatory factors (IL-1b, TNF-α),serum antioxidant status includin ((total antioxidant capacity (TAC), malondialdehyde (MDA), Activity of superoxide dismutase enzyme (SOD), Activity of glutathione peroxidase enzyme (GSHPx), Activity of catalase enzyme)) ; 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: **IRCT2017030831993N4**
Registration date: **2017-06-01, 1396/03/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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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

2017-05-27, 1396/03/06

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melatonin supplement with Non surgical periodontal therapy on periodontal status, some inflammatory markers and serum antioxidant status in type 2 diabetic patients with chronic periodontitis.

Public title
The effect of melatonin supplementation in the treatment of type 2 diabetic patients
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 < 30kg/m2. 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: **50**
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 Joudishapour University of Medical Science
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran Ahvaz
City
Ahvaz
Postal code
61357-15794
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
IR.AJUMS.REC.1396.157

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

2

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

3

Description
IL-1b
Timepoint
Before and after the intervention
Method of measurement
ELISA

4

Description
Total antioxidant capacity (TAC)
Timepoint
Before and after the intervention
Method of measurement
ELISA

5

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

6

Description
Activity of superoxide dismutase enzyme (SOD)
Timepoint
Before and after the intervention
Method of measurement

ELISA

7

Description
Activity of Glutathione peroxidase enzyme (GSHPx)
Timepoint
Before and after the intervention
Method of measurement
ELISA

8

Description
Activity of Catalase enzyme (GSHPx)
Timepoint
Before and after the intervention
Method of measurement
ELISA

9

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

10

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

11

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
Hadi Bazyar
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran
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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
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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
Hadi Bazyar
Position
Msc Student of Nutrition
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Person responsible for scientific inquiries

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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