

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of systemic melatonin and non surgical periodontal therapy on serum ferritin inpatients with periodontitis disease

Protocol summary

Study aim

1. Determination and comparison of serum ferritin in patients with periodontitis before intervention after non-surgical periodontitis treatment and after non-surgical periodontitis treatment with administration of melatonin system 2. Determination and comparison of periodontal clinical parameters before and after the intervention in two case control groups.

Design

The randomized double-blinded clinical trial

Settings and conduct

42 patients with moderate periodontitis referred to Tabriz Dental School are selected and periodontal parameters will be recorded and a blood sample will be taken. After SRP, all patients will receive mouthwash and will be randomly divided into 2 groups. In the intervention group, chlorohexidine mouthwash and oral administration of melatonin tablets will be given for 30 days and in the control group, chlorhexidine will be administered. After 30 days and three months, blood samples will be taken to determine serum ferritin levels.

Participants/Inclusion and exclusion criteria

En Entry criteria: 1.Lake of loss the joints in interdental areas larger than 4 mm. 2.Absent depth of the envelope larger than 4 mm in the interdental areas. The bleeding tendency is less or equal to 10% in total Exit criteria:1.People with systemic disorders 2. Invader Periodontium 3. Smokers and Alcoholics 4. Pregnancy or breastfeeding 5. Patients taking medications that can affect the level of melatonin 6. Those who have had periodontal treatment in the last 6 months. 7.People working in night shifts. 8.Under-20s. 9.People with mental disabilities

Intervention groups

In the intervention group (21 patients), chlorohexidine was administered 12% twice daily for 30 seconds for two weeks. And taking oral melatonin 3 mg daily for one day for 30 days

Main outcome variables

ferritin levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100412003690N9**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **retrospective**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Masoomeh Faramarzie

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1385 4863

Email address

faramarzim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-26, 1397/09/05

Expected recruitment end date

2018-12-01, 1397/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of systemic melatonin and non surgical periodontal therapy on serum ferritin inpatients with periodontitis disease

Public title

Effects of systemic melatonin and non surgical periodontal therapy on serum ferritin inpatients with periodontitis disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Lack of loss the joints in interdental areas larger than 4 mm. 2. Absent depth of the envelope larger than 4 mm in the interdental areas. 3. The bleeding tendency is less or equal to 10% in total. 4. Age older than twenty years

Exclusion criteria:

1. People with systemic disorders, such as epilepsy, schizophrenia, chronic infections, neoplastic disease, or any disease that affects the immune system. 2. Invader Periodontium 3. Smokers and Alcoholics 4. Pregnancy or breastfeeding 5. Patients taking medications that can affect the level of melatonin 6. Those who have had periodontal treatment in the last 6 months. 7. People working in night shifts. 8. Under-20 years. 9. People with mental disabilities

Age

From 20 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Referring patients with periodontitis to Tabriz Faculty Of Dentistry are numbered, after observing the entry and exit requirements of the study. Then, using a random number table, we select 42 numbers from this table and enter the subject.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participating patients and physician will be informed of the type of treatment intervention (1- Chlorhexidine mouthwash 2- Melatonin oral administration), however, the evaluator of the results will not be aware of the intervention method, so the study will be single-blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615953

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.TBZMED.REC.1397.664

Health conditions studied

1

Description of health condition studied

Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

serum ferritin level

Timepoint

Before the start, One and three months later

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Vi-One chlorhexidine 2% mouthwash will be used for one minute to wash teeth

in the morning and at night, and oral melatonin tablets will be taken for a period of 30 days once a day before bedtime.

Category

Treatment - Drugs

2**Description**

Control group: Chlorhexidine mouthwash for 30 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

Full name of responsible person

Masoumeh Faramarzi

Street address

Golgasht Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

faramarzim@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Jouyban

Street address

Golgasht Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

faramarzim@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Golgasht Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

faramarzim@tbzmed.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Golgasht Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

faramarzim@tbzmed.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Golgasht Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

faramarzim@tbzmed.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the participants can be presented in the form of a table. The protocol for the study, which is routine methods, has no problems with its publication. Statistical analysis can also be provided. In this study, an informed consent form will be used that can be published without mentioning the person's name and personal details. A clinical study report can be made after the necessary analyzes.

When the data will become available and for how long

Start the access period 9 months after publishing the results

To whom data/document is available

For researchers in Dental school of Tabriz University

Under which criteria data/document could be used

For scholars working in other academic and academic institutions, if approved by the project implementer

From where data/document is obtainable

Dr. Masoomeh Faramarzi, email or phone Dental school of Tabriz University, Periodontics department, 9144113420 0098 , faramarzim@tbzmed.ac.ir

What processes are involved for a request to access data/document

After receiving the request will be answered within a week.

Comments