

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effects of antioxidant supplements melatonin alone and in combination with vitamin C on the clinical characteristics of periodontal treatment phase

Protocol summary

Summary

The purpose of this study was to evaluate the antioxidant effects of melatonin, melatonin and vitamin C alone and synergistic effects on periodontal clinical parameters. The study is a randomized, double-blind, placebo-controlled, single-center, phase one trial takes place. In this study, 69 patients older than 20 years will be enrolled with the following criteria: 1. Patients with moderate periodontitis, teeth excluding third molars 2. Patient must have a function 3. Lack of Systemic 4 - Full mouth score plaque above the 25%, 5 non-use of antibiotics in the previous quarter and exclusion criteria of the study are as follows: 1. pregnancy and breastfeeding (2) systemic disease; (3) the use of any medication placed in the hands of patients and classified the patients in the study group for the Blind before entering the study will be: 1 Protocol 1 (treatment phase): first, for each patient after charting, oral hygiene instruction is given and in charting index PD, BOP, CAL, plaque index, measured by the periodontist is unaware of the study. Pocket depth and attachment level measurements are performed in six areas of each tooth. Measuring the adhesion of the stent edges of preparation done before, then 1 patients treated with scaling and root Brvsazh the smooth surface in two sessions a week are at a distance. And for this purpose hand tools, devices and will be used Rabrpk and pumice paste and placebo in the form of a supplement to other patients are prepared. 2. Protocol 2 (Phase One treatment with melatonin administration): the implementation of the protocols 1, 2 mg melatonin supplement prescription pill, a pill every night for 30 days 3. Protocol 3 (Phase One treatment with melatonin administration and vitamin C), the performance of all acts of protocol 1, prescribe supplements of melatonin 2mg per night a 30-day prescription pill vitamin for women and 60 mg for men and 75 mg three times per

day for 30 day clinical parameters before treatment and after 3 and 6 months post-treatment evaluation include: the primary outcome variable clinical attachment level (CAL) and secondary outcome variables bleeding during probing (BOP), probing depth (PD), plaque index. CAL, BOP and PD are measured by periodontal probe and plaque index is measured by the detector tablets

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112410155N2**

Registration date: **2015-02-15, 1393/11/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

Name

Mohammad Taghi Chitsazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-09, 1393/09/18

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of antioxidant supplements melatonin alone and in combination with vitamin C on the clinical characteristics of periodontal treatment phase

Public title

Effects of melatonin alone and with vitamin C in the treatment of periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Patients older than 20 years old with will be enrolled with the following criteria : 1. Patients with Moderate periodontitis; 2. Patients must have teeth excluding third molars in function 3. The absence of systemic disease 4. Full mouth score plaque above 25%; 5 .Non- use of antibiotics in the last three months 6. Willingness to participate in the study. Exclusions criteria of the study are as follow: 1. Pregnancy and lactation; 2. Systemic disease; 3. Of any kind of drugs , tabaco, alcohol; 4. Failure to establish any of the terms of inclusion

Age

From 20 years old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**

Target sample size: 69

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

Tabriz University of Medical Ethics

Street address

Street camping , Tabriz University of Medical Sciences , Tabriz University of Medical Sciences , Tabriz University of Medical Ethics

City

Tabriz University of Medical Ethics

Postal code

5166614713

Approval date

2014-12-08, 1393/09/17

Ethics committee reference number

93133

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

Relationship between antioxidant supplements with melatonin alone and Bavytamyn C on clinical periodontal index of treatment phase

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Clinical attachment level (CAL)

Timepoint

Before the experiment (Baseline) , 3 months after the intervention, 6 month after the intervention

Method of measurement

Measured the distance between the bottom of the stent sulcus by periodontal probe

Secondary outcomes**1****Description**

plaque

Timepoint

Before the experiment , (Baseline) , 3 months after the intervention, 6 months after intervention

Method of measurement

Disclosing agent by visual scale

2**Description**

Bleeding on probing (BOP)

Timepoint

Before the experiment (Baseline) , 3 months after the intervention, 6 months after intervention

Method of measurement

Bleeding for 15 seconds after gentle probing by periodontal probe

3

Description

Probing depth (PD)

Timepoint

Before the experiment, three months after the intervention, six months after the intervention

Method of measurement

The distance between the bottom of the sulcus by marginal mucosa and periodontal probe in mm

Intervention groups

1

Description

Control chart completion, scaling and brushing by handheld devices, ultrasonic and Rabrpk and paste pumice, administered placebo for 30 days.

Category

Placebo

2

Description

Group 2 (intervention), chart completion, scaling and brushing by handheld devices, ultrasonic and Rabrpk and paste pumice, administration of melatonin tablets 2 mg, once a day, for 30 days

Category

Treatment - Drugs

3

Description

Group 3 (intervention), chart completion, scaling and brushing by handheld devices, ultrasonic and Rabrpk and pumice paste, oral administration of melatonin 2 mg, once a day, for 30 days and 60 mg vitamin C tablets prescribed for women and 75 mg for men, 3 time a day, for 30 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gum disease and tooth Research Center, School of Dentistry, Tabriz

Full name of responsible person

Dr mohammad Taghi Chitsazi

Street address

University Circle - University Avenue - Tabriz
University of Medical Sciences - Faculty of Dentistry, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, School of Dentistry, Tabriz, gum disease and tooth Research C

Full name of responsible person

Dr Reza Pourabbas and Dr Rahimi

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The Islamic Republic of Iran, East Azerbaijan, Tabriz, University Circle, University Avenue, Tabriz University of Medical Sciences, School of Dentistry, Tabriz

City

Tabriz

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, School of Dentistry, Tabriz, gum disease and tooth Research C

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

Gum disease and tooth Research Center, School of Dentistry, Tabriz

Full name of responsible person

Dr Mohammad Taghi Chitsazi

Position

Associate Professor of Periodontics, Division of Periodontics specialist

Other areas of specialty/work

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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