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 l 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 Rabrkp 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)

Phone

+98 41 1335 5965

Email address

chitsazm@tbzmed.ac.ir

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 periodotitis; 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 Scienses , 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
Befoer 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 afte ther intervention
Method of measurement
Disclosing agent by visual scale

2

Description
Bleeding on probing (BOP)
Timepoint
Before the experiment (Baseline) , 3 months afterthe intervention, 6 months afterintervention
Method of measurement
Bleedingfor 15 seconds afte rgentle 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 Rabrkp 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 Rabrkp 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 Rabrkp 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 Dentisty,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
Street address
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
Street address
The Islamic Republic of Iran, East Azerbaijan, Tabriz, University Circle, University Avenue, Tabriz University of Medical Sciences, School of Dentistry, Tabriz
City
Tabriz
Postal code
5166614711
Phone
00
Fax
Email
mtchitsazi@gmail.com
Web page address

Person responsible for scientific 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

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

City
Tabriz

Postal code
5166614711

Phone
+98 41 3335 5965

Fax
+98 41 3334 6977

Email
mtchitsazi@gmail.com

Web page address
http://dentistryfac.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Gum disease and tooth Research Center, School of Dentistry, Tabriz

Full name of responsible person
Arash Hashemzadeh

Position
Student Dental

Other areas of specialty/work

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

City
Tabriz

Postal code
5166614711

Phone
00

Fax

Email
Arash_hs2012@yahoo.com

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