Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of supplementation of Q10 coenzyme with Scaling and root planing (SRP) on periodontal and gingival indexes in controled diabetic patients

Protocol summary

Study aim
The effect of supplementation of Q10 coenzyme with Scaling and root planing (SRP) on periodontal and gingival indexes in controled diabetic patients

Design
Clinical trial with parallel intervention group, One-way blind, Random, The sampling method is random. The randomization method is simple and with a table of random numbers. 42 people selected (21 patients prescribed coenzyme Q10 plus SRP for 30 days, 21 patients in the control group prescribed only SPR)

Settings and conduct
The study will be performed in the periodontics department of Tabriz Dental School. 21 patients in the intervention group prescribed coenzyme Q10 plus SRP for 1 mount, 21 patients in the control group prescribed only SPR. The evaluator and the patient are unaware of the type of treatment. The periodontics indexes will evaluate after 1 mount.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Loss of joints up to 4 mm in the area between dental, envelope depth up to 5 mm in the interdental area Exclusion criteria: People with systemic disorders such as epilepsy, schizophrenia, chronic infection, neoplastic disease or any disease that affects the immune system, Invasive periodontitis, Smokers or alcoholics, Pregnancy or lactation, Patients who use drugs that can affect the level of melatonin, People who had periodontal treatments in the last 6 months, Persons under 20 years, Mentally disabled people, Patients who use blood-thinning drugs and beta-blocker, Patients who are taking insulin, People with cardiovascular disease, People with thyroid disorders, Any symptoms of allergies to Quenzyme Q10 , Individuals with an inappropriate cooperation and change in the drug regime

Intervention groups
Coenzyme Q10 administration with SRP for 30 days in the intervention group and SRP administration for 30 days in the control group

Main outcome variables
Plaque index;Clinical Attachment Level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180630040290N4**
Registration date: **2020-08-06, 1399/05/16**
Registration timing: **retrospective**

Last update: **2020-08-06, 1399/05/16**
Update count: **0**

Registration date
2020-08-06, 1399/05/16

Registrant information

Name
Amir Reza Babaloo

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-25, 1399/05/04

Expected recruitment end date
2020-08-06, 1399/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation of Q10 coenzyme with Scaling and root planing (SRP) on periodontal and gingival indexes in controled diabetic patients

Public title

Effect of coenzyme Q10 supplement on chronic gingivitis inflammation in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients referred to the periodontitis Department of Tabriz Dental School Having informed consent Having age 29 to 59

Exclusion criteria:

People with systemic disease Pregnant women

Age

From **29 years** old to **59 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

Sampling method is randomly available among individuals referring to periodontics department of Tabriz dental faculty. The randomization method is simple and the unit is individual, our tool for randomization is the randomized number chart. Furthermore, the allocation of traetment to patients is done randomly. To do this, the types of the traetment are identified with code A (Q10 coenzyme with Scaling and root planing (SRP)) and B (SPR) and then the traetment are sealed in envelopes that will be placed in a box and stirred. Then they are randomly chosen from the box and after observing the code, the traetment is given to the patient. None of the patients will be informed about another patient's traetment. The a evaluater will olso be is not informed about type of traetment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is one-way blind and the a evaluater will olso be is not informed about type of traetment.

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

Central office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

City

Tabriz

Province

East Azarbaijan

Postal code

5165687386

Approval date

2020-07-20, 1399/04/30

Ethics committee reference number

IR.TBZMED.REC.1399.442

Health conditions studied

1

Description of health condition studied

Controlled diabetes

ICD-10 code

E10.6

ICD-10 code description

Type 1 diabetes mellitus with other specified complications

Primary outcomes

1

Description

Pocket Depth

Timepoint

Before the intervention , one months after initiating the intervention

Method of measurement

A periodontal probe is used to measure this parameter. The first sign visible at the top of the envelope is the depth of the envelope.

2

Description

Clinical Attachment Level

Timepoint

Before the intervention , one months after initiating the intervention

Method of measurement

The clinical adhesion of the gums is obtained by the difference between the distance from the gingival margin

to the plaque floor from the CEJ distance to the gingival margin.

Secondary outcomes

1

Description
Plaque index
Timepoint
Before the intervention , one months after initiating the intervention
Method of measurement
Plaque index is obtained from dividing the number of levels with plaque on the total number of multiplication levels in 100 .

2

Description
Bleeding index
Timepoint
Before the intervention , one months after initiating the intervention
Method of measurement
Bleeding index (BI) is measured using the University of North Carolina probe_15 (UNC-15) probe.

Intervention groups

1

Description
Intervention group:Coenzyme Q10 will be administered with SRP for 30 days, after which periodontal and gingival index values will be measured. Patients were randomly divided into two groups and will given 200 mg of coenzyme Q10 or placebo daily for 30 days. For all patients, coenzyme Q10 prescription and oral hygiene training and accurate SRP will performe by a therapist in a one-hour session. For this purpose, hand tools, ultrasonic and rubber cap and pumice paste will be used.
Category
Treatment - Drugs

2

Description
Control group: The SRP will be prescribed for 30 days and then relating to periodontal and jinjal indicators will be measured
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences Dentistry Faculty Periodontics Department
Full name of responsible person
Amirreza Babaloo
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Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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

Amir reza Babaloo

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available