

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of supplementation of Q10 coenzyme with Scaling and root planing (SRP) on periodontal and gingival indexes in controlled 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 controlled 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 month, 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 month.

##### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3428 3025

##### Email address

babalooa@tbzmed.ac.ir

##### 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 controlled 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 treatment to patients is done randomly. To do this, the types of the treatment are identified with code A (Q10 coenzyme with Scaling and root planing (SRP)) and B (SPR) and then the treatment 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 treatment is given to the patient. None of the patients will be informed about another patient's treatment. The evaluator will also be is not informed about type of treatment.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The present study is one-way blind and the evaluator will also be is not informed about type of treatment.

**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

#### Street address

Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614711

#### Phone

+98 41 3335 5921

#### Email

amirrezababaloo@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammad Samiei

##### Street address

Central office No. 2, Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 7310

##### Email

ajouyban@hotmail.com

#### 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

**Street address**

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5921

**Email**

amirezababaloo@yahoo.com

**Person responsible for scientific 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

**Street address**

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5921

**Email**

amirezababaloo@yahoo.com

**Person responsible for updating data**

**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

**Street address**

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5921

**Email**

amirezababaloo@yahoo.com

**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