

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Clinical and metabolic changes after subgingival insertion of xanthan-based chlorhexidin gel in type 2 diabetic patients with chronic periodontitis.

Protocol summary

Summary

After approval of input and output criteria, Patients were selected in 2 groups: 33 Patients had gotten diabetes 2 and Chronic periodontists. This study had been on Split mouth method. All patient were belonged to both groups (Control Group and Test Group). For control Group SRP lonely and for test group both SRP and Chlorhexidine gel were Injected. In this study, whole the mouth were made SRP by Ultrasonic equipment. Then the test area were washed by cold saline. 10 Minutes waiting were considered to make homeostasis completed. Chlorhexidine gel were injected to the deepest area of package by special needle injector (Round Bottom), and then a periodontal pack were placed in the area by no pressure. Health educations like how to toothbrush were thought to patient in case patient was not allowed to use mouthwash or any other mouth washing products. After one week patient was visited for removal of the periodontal pack. The following sessions were held after 3 and 6 months. Any Sub-gingival instrumentation were done in the area, following meetings were held just to register clinical parameters and Metabolic control plaques of the patient. HbA1c and FBS tests were asked for all patients and all of them were referred to a specific laboratory. All clinical parameters were reviewed in the beginning and then in next 3 and 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411023690N5**

Registration date: **2015-07-17, 1394/04/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-17, 1394/04/26

Registrant information

Name

Masoomeh Faramarzie

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Goverment

Expected recruitment start date

2014-12-09, 1393/09/18

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and metabolic changes after subgingival insertion of xanthan-based chlorhexidin gel in type 2 diabetic patients with chronic periodontitis.

Public title

Effect of Chlorhexidine gel in diabetic and gum disease patients

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: presence of type 2 diabetes ; HbA1c $\geq$ 6.0% ; Clinical Diagnosis of moderate generalized chronic periodontitis defined by loss of clinical attachment more than 3mm and bone loss more than 30% ; Presence of more than 10 teeth per dental arch, excluding third molars ; No previous periodontal treatment taken ; signing informed consent, and commitment to post treatment follow-up visits ; no modification in medication for two months, before or during the study exclusion criteria: Presence of systemic disease that could influence the course of periodontal disease ; Intake of anti-inflammatory antibiotics for four weeks before the study ; current smokers or ex-smokers of <5 years ; Pregnancy or intention to be pregnant during the six months of study ; Intake of periodontal treatment in 3 months ago ;

Age
 From **30 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **33**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics Committee Of Tabriz Medical University

Street address
 Street camping , Tabriz University of Medical Sciences , Tabriz University of Medical Sciences , Ethics Committee Of Tabriz Medical University

City
 Tabriz

Postal code
 5166614713

Approval date
 2014-12-08, 1393/09/17

Ethics committee reference number

93137

Health conditions studied

1

Description of health condition studied

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic pericoronitis Periodontitis: NOS complex simplex

Primary outcomes

1

Description

HbA1c

Timepoint

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

Method of measurement

Examination

Secondary outcomes

1

Description

Fast Blood Sugar (FBS)

Timepoint

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

Method of measurement

Examination

2

Description

Clinical attachment level (CAL)

Timepoint

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

Method of measurement

with periodontal prob from CEJ to pocket depth

3

Description

Probing depth (PD)

Timepoint

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

Method of measurement

with periodontal prob

4

Description

plaque Index

Timepoint

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

Method of measurement
Disclosing tablets

5

Description
Bleeding Index (BI)

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

Method of measurement
observe

Intervention groups

1

Description
chart completion, scaling and brushing by handheld devices, ultrasonic and Rabrpk and paste pumice in treatment during, injected the chlorhexidin within gingiva

Category
Treatment - Drugs

2

Description
chart completion, scaling and brushing by handheld devices, ultrasonic and Rabrpk and paste pumice

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 Masoumeh Faramarzi
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
Vice Chancellor for research of Tabriz University of Medical Sciences, School of Dentistry, Tabriz,
Full name of responsible person
Dr Reza Pour Abbas

Street address
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
Vice Chancellor for research of Tabriz University of Medical Sciences, School of Dentistry, Tabriz,
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 Masoumeh Faramarzi
Position
Associate Professor of Periodontics / teacher of university
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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
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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

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

Sahand Ghani Tab

Position

Student Dental

Other areas of specialty/work**Street address**