

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

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Name of organization / entity

Tabriz University of Medical Sciences

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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	93137
Inclusion/Exclusion criteria	Health conditions studied
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 ;	1
Age	Description of health condition studied
From 30 years old to 70 years old	chronic periodontitis
Gender	ICD-10 code
Both	K05.3
Phase	ICD-10 code description
N/A	Chronic pericoronitis Periodontitis: NOS complex simplex
Groups that have been masked	Primary outcomes
No information	1
Sample size	Description
Target sample size: 33	HbA1c
Randomization (investigator's opinion)	Timepoint
Not randomized	Before the experiment, three months after the intervention, six months after the intervention
Randomization description	Method of measurement
Blinding (investigator's opinion)	Examination
Not blinded	Secondary outcomes
Blinding description	1
Placebo	Description
Not used	Fast Blood Sugar (FBS)
Assignment	Timepoint
Parallel	Before the experiment (Baseline) , 3 months after the intervention, 6 month after the intervention
Other design features	Method of measurement
	Examination
Secondary Ids	2
empty	Description
	Clinical attachment level (CAL)
Ethics committees	Timepoint
1	Before the experiment (Baseline) , 3 months after the intervention, 6 month after the intervention
Ethics committee	Method of measurement
Name of ethics committee	with periodontal prob from CEJ to pocket depth
Ethics Committee Of Tabriz Medical University	3
Street address	Description
Street camping , Tabriz University of Medical Sciences , Tabriz University of Medical Sciences , Ethics Committee Of Tabriz Medical University	Probing depth (PD)
City	Timepoint
Tabriz	Before the experiment (Baseline) , 3 months after the intervention, 6 month after the intervention
Postal code	Method of measurement
5166614713	with periodontal prob
Approval date	4
2014-12-08, 1393/09/17	Description
Ethics committee reference number	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

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor of Periodontics

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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**