

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of salivary IL-1 beta in moderate to severe chronic generalized periodontitis among healthy subjects and patients with type 2 diabetes

Protocol summary

Summary

Periodontitis is periodontal inflammation that that exceeded and damage to attachment tissues around the teeth. Diabetes is a risk factors in periodontal disease. So far, many studies have shown that there is significant association between periodontitis and types of salivary biomarkers such as MMP-8, IL-1B, CRP, TNF α , IGA .In the present study, will try to compare salivary interleukin-1 beta in diabetic patients with chronic periodontitis and generalized chronic periodontitis and generalized normal blood sugar, review effect of diabetes on the severity of chronic generalized periodontitis. The target population is a patients with chronic generalized periodontitis with diabetes and without diabetes. During the six months, the current study will be, from firs of October 2014 to the end of March in the Tabriz Oral Medicine and Periodontics Department, School of Dentistry. Random sampling would be that will be selected number 56 patients from referred to that center. Inclusion criteria: having the history of type 2 diabetes or people who have more than 2 consecutive blood glucose levels more than 126 mg / dl; the average age of 40-60 years old; having chronic generalized periodontitis that have more than 30% attachment lose; willing to participate in the study. Exclusion criteria: unwillingness to participate in the study; any systemic disease other than diabetes and debilitating diseases that can effect on oral health person's; any non-surgical periodontal therapy that has been done over the last 9 months; smoking or quit smoking less than 5 years; pregnancy or intend to become pregnant during the study period of 6 month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110916246N2**

Registration date: **2014-11-27, 1393/09/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-27, 1393/09/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-08, 1393/01/19

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of salivary IL-1 beta in moderate to severe

chronic generalized periodontitis among healthy subjects and patients with type 2 diabetes	2014-11-10, 1393/08/19 Ethics committee reference number 93122
Public title Comparison of salivary IL-1 beta in moderate to severe chronic generalized periodontitis among healthy subjects and patients with type 2 diabetes	Health conditions studied 1 Description of health condition studied Diabetes Mellitus ICD-10 code E11 ICD-10 code description Non-insulin-dependent diabetes mellitus
Purpose Diagnostic Inclusion/Exclusion criteria Inclusion criteria: having the history of type 2 diabetes or people who have more than 2 consecutive blood glucose levels more than 126 mg / dl; the average age of 40-60 years old; having chronic generalized periodontitis that have more than 30% attachment lose; willing to participate in the study. Exclusion criteria: unwillingness to participate in the study; any systemic disease other than diabetes and debilitating diseases that can effect on oral health person's; any non-surgical periodontal therapy that has been done over the last 9 months; smoking or quit smoking less than 5 years; pregnancy or intend to become pregnant during the study period of 6 month.	Primary outcomes 1 Description IL-1beta Timepoint Before intervention Method of measurement ELISA
Age No age limit Gender Both Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 56 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 outcomes 1 Description generalized chronic periodontitis and chronic periodontitis with diabetes and without diabetes Timepoint Before intervention Method of measurement PD,CAL, BOP PI, FBS, HbA1c
Secondary Ids empty	Intervention groups 1 Description Saliva was collected in the intervention group and the control group Category Early detection
Ethics committees 1 Ethics committee Name of ethics committee Dental and Periodontal Research Cente Street address Tabriz University of Medical Sciences City tabriz Postal code Approval date	Recruitment centers 1 Recruitment center Name of recruitment center Department of Oral Medicine and Periodontics Department Full name of responsible person Nazila Sadeghi Street address Tabriz University of Medical Sciences, Faculty of Dentistry

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice-chancellor

Full name of responsible person

Dr. Saied Rahimi

Street address

Tabriz Faculty of Dentistry

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Vice-chancellor

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

Dental and Periodontal Research Center

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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