

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

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.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

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 Ids

empty

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

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

IL-1beta

Timepoint

Before intervention

Method of measurement

ELISA

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

Intervention groups

1

Description

Saliva was collected in the intervention group and the control group

Category

Early detection

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

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Vice-chancellor

Full name of responsible person

Dr. Saied Rahimi

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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

Full name of responsible person

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Assistant Professor

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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*