

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of proinflammatory cytokines levels in gingival crevicular fluid around dental implants with Zirconia and titanium abutments

Protocol summary

Summary

Abutments are one of the important components of implant dependent restorations and two types of recommended abutments are ceramic and titanium abutments. One of the common problems after reconstruction of dental implants is gingivitis around the implant. Of the most important inflammatory cytokines are IL- β 1 and IL-6 which have similar effects and synergistic. The aim of this study is the evaluation and comparison of proinflammatory cytokines levels in gingival crevicular fluid around dental implants with zirconia and titanium abutments until introduce the best compatible one. All patients with implant that referred to prosthesis specialist private office, in the June up to August 2016 examine about implant success and patient with implants according to inclusion criteria will entered to one of the two study groups (the first group have ceramic abutment and second group have titanium abutment). Samples are achieved from peri- implant sulcus and paper points are entered to four specific areas (mesiobuccal, distibuccal, mesiolingual and distolingual) for gingival crevicular fluid sampling until modest resistance will be felt and will be kept there for 30 seconds. Any paperpoint placed inside a small sterile tube and then are frozen in -80 °C until all samples are prepared. Proinflammatory cytokines of IL6 and IL1 β will be measured in the Immunology laboratory by ELISA kit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123020488N1**

Registration date: **2016-07-13, 1395/04/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of proinflammatory cytokines levels in gingival crevicular fluid around dental implants with Zirconia and titanium abutments

Public title

Comparison of proinflammatory factors levels in gingival crevicular fluid around dental implants

Purpose

Prevention

Inclusion/Exclusion criteria

• inclusion criteria of the study: 1-Having at least two units of the posterior dental implants around tooth of 6 or 7 in two-sided at the same jaw 2. Having at least 1 mm attached gingiva around the implant 3-Maximum thickness of gingiva in the neck of the implant to be 3 mm. 4. Having at least 18 years-old • Exclusion criteria of the study: 1.Scaling and Root planning in the past three months 2. Pregnant women and nursing mothers 3. Patients receiving antibiotics in the past 6 months 4. Having any systemic diseases like diabetes that affect on oral health 5. Drug addiction, smoking or alcohol 6. A history of the use of the bisphosphonates 7. Taking systemic anti-inflammatory medications

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research (VCR) of Tabriz
University of Medical Sciences

Street address

Tabriz-Golgasht St.

City

tabriz

Postal code

Approval date

2016-07-05, 1395/04/15

Ethics committee reference number

IR.TBZMED.REC.1395.277

Health conditions studied

1

Description of health condition studied

implantitis

ICD-10 code

T85.9

ICD-10 code description

Unspecified complication of internal prosthetic device, implant and graft

Primary outcomes

1

Description

IL6 - IL1 β

Timepoint

before intervention- 4 month after intervention

Method of measurement

ELISA Kit

Secondary outcomes

empty

Intervention groups

1

Description

This study is split-mouth study, in on side ceramic abutment will be used and another side titanium abutment

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

private office of Prosthesis specialist

Full name of responsible person

Street address

City

tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

sarvar alipur

Street address

tabriz- golgasht avenue -Vice Chancellor for Research and Technology

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 and Technology
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

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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