

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of effect of abutment removal and reconnection on increasing inflammatory factors around dental implants in multi-unit abutment with conventional abutment

Protocol summary

Summary

The aim of this study is evaluation of inflammatory cytokines, IL6 and IL1 β in gingival crevicular fluid of implants in two methods of making a standard implant (impression in fixture level) and a new protocol (impression in Multi-unit abutment surface). 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 participated to one of the two study groups (25 person in each group). Study was clinical trial (split-mouth) and one side blind and making of dental implant prosthesis in one side of the jaw done by multi-unit abutment and in another side healing abutment put on implant and impression is done on the fixture surface. On the side that the healing abutment was used, abutment will opened and closed at least three times. Samples are achieved from peri- implant sulcus and paper points are entered to four specific areas (mesiobuccal, distobuccal, mesiolingual and distolingual) for gingival crevicular fluid sampling until modest resistance will be felt and will be kept there for 30 seconds. Any paper point placed inside a small sterile tube and then are frozen in -80 °C until all samples are collected. 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: **IRCT2016071120488N2**

Registration date: **2016-08-15, 1395/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name

Ramin Negahdari

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 912 607 0035

Email address

negahdarir@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2016-05-31, 1395/03/11

Expected recruitment end date

2016-08-03, 1395/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of abutment removal and reconnection on increasing inflammatory factors around dental implants in multi-unit abutment with conventional abutment

Public title

Comparison of effect of abutment removal and

reconnection on increasing inflammatory factors around dental implants in multi-unit abutment with conventional abutment

Purpose

Prevention

Inclusion/Exclusion criteria

- Inclusion criteria of the study: Having informed consent for inclusion to study; Having at least two units of the posterior dental titanium implants in two-sided at the same jaw; Putting implants under two-stage process that demands exposure in the second stage of surgery; Having at least 2 mm attached gingiva around the implant; 5. Maximum thickness of gingiva in the neck of the implant to be 3 mm; Having at least 18 years-old • Exclusion criteria of the study: Scaling and Root planning in the past three months; People who need bone augmentation and with periodontitis; People who underwent radiotherapy within the past year in the head and neck areas; Pregnant women and nursing mothers; Patients receiving antibiotics in the past 6 months; Having any systemic diseases like diabetes that affect on oral health; Drug addiction, smoking or alcohol; A history of the use of the bisphosphonates; Taking systemic anti-inflammatory medications

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz-Golgasht St.

City

Tabriz

Postal code

Approval date

2016-07-19, 1395/04/29

Ethics committee reference number

IR.TBZMED.REC.1395.302

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

Intervention1: In on side multi-unit abutment will be used.

Category

Treatment - Devices

2

Description

Intervention2: In another side, common abutment will be used.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office of prosthesis specialist

Full name of responsible person

Street address

Daneshgah square

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

Sarvar Alipur

Street address

Thir floor, Central building of number 2, Golgasht street, 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 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

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr Ramin Negahdari

Position

Phd in prosthodontics

Other areas of specialty/work

Street address

dentistry faculty, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3440 9387

Fax

Email

negahdarir@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr Ramin Negahdari

Position

Phd in prosthodontics

Other areas of specialty/work

Street address

Dentistry faculty, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3440 9387

Fax

Email

negahdarir@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Ebrahim Taghavi

Position

Other areas of specialty/work

Street address

Dentistry faculty, Golgasht street, Tabriz

City

tabriz

Postal code

Phone

+41 33344280

Fax

Email

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