

# 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 $\beta$  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 $\beta$  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 $\beta$

##### **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*