

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of antiseptic and antibiotic usage within the implant on the pro-inflammatory cytokines interleukin 1 β and interleukin 6 in gingival crevicular fluid for the contact of the implant and abutment

Protocol summary

Study aim

Control of inflammation around dental implants in order to reduce the amount of bone erosion around the implant neck, the health of surrounding soft tissues and increase the efficiency of dental implant

Design

Clinical trial with 24 samples in 3 groups

Settings and conduct

Each of the materials examined at an uncovering session is placed inside the implant bolt and the healing screw is closed. Then, in three sessions of Prosthesis Delivery Molding and one month after the delivery of the prosthesis, samples are taken from the patients. Each area is isolated by cotton roll and is airborne for 5 seconds to dry out any salivary contamination from the area. These paper points are inserted into four distinct regions (mesiobuccal, distobuccal, mesiolingual and distolingual) into the gingival groin and held for 30 seconds. Any tissue that looks at the blood contamination will be discarded. Then, immediately any paper clip inside the small sterile tubes containing the buffer fluid and then placed at -80 ° C until all samples are freeze. Samples will be sent to the Immunology Laboratory to measure the pre-inflammatory cytokines IL6 and IL1 β by the ELISA kit.

Participants/Inclusion and exclusion criteria

Criteria for entering: Have at least 3 implants in one jaw Having at least 18 years of age The probe depth around the implant between 1-3 mm Criteria for exiting: People have been scaling in the last three months in the last three months Pregnant and lactating women Patients receiving antibiotics in the last 6 months Having any systemic disease, such as diabetes, that affects oral health

Intervention groups

Intervention group: The study is split mouth and each patient will have 3 different environments chlorohexidine

2%, tetracycline 3% and dry environments in each implant.

Main outcome variables

inflammation Inflammation of the implant and abutment contact point

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043702N1**

Registration date: **2019-06-05, 1398/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-05, 1398/03/15**

Update count: **0**

Registration date

2019-06-05, 1398/03/15

Registrant information

Name

Ramin negahdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

ramin_ndds@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of antiseptic and antibiotic usage within the implant on the pro-inflammatory cytokines interleukin 1 β and interleukin 6 in gingival crevicular fluid for the contact of the implant and abutment

Public title

Effect of antiseptic and antibiotic usage within the implant in gingival crevicular fluid for the contact of the implant and abutment

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least 3 implants in one jaw Having at least 18 years of age The probe depth around the implant between 1-3 mm

Exclusion criteria:

People have been scaling in the last three months in the last three months Pregnant and lactating women Patients receiving antibiotics in the last 6 months Having any systemic disease, such as diabetes, that affects oral health Drug addiction, cigarette or alcohol History of the use of bisphosphonates History of the use of bisphosphonates

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **24****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**

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz University of Medical Sciences, Daneshgah St.

City

tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.TBZMED.REC.1398.166

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**Interleukin 1 β **Timepoint**

1 month

Method of measurement

Elisa kit

2**Description**

Interleukin 6

Timepoint

1 month

Method of measurement

Elisa kit

Secondary outcomes

empty

Intervention groups**1****Description**

First Intervention group: The study is split mouth and each patient will have chlorohexidine 2% in first implant.

Category

Diagnosis

2**Description**

Second Intervention group: The study is split mouth and each patient will have tetracycline 3% in second implant.

Category

Diagnosis

3**Description**

Third Intervention group: The study is split mouth and each patient will have Saliva in third implant.

Category

Diagnosis

4**Description**

Control group: The study is split mouth and each patient will have dry environments in control implant.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Dental Faculty, Dental Prosthodontics
Department

Full name of responsible person

Dr. Ramin Negahdari

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Goltasht Street, Tabriz Dental Faculty

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Reza Pourabbas

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ramin Negahdari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data has subscription capability

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

All people

Under which criteria data/document could be used

No specific case

From where data/document is obtainable

Email Dr. Negahdari

What processes are involved for a request to access data/document

No specific case

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ramin Negahdari

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