

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

An evaluation to compare peri-implant crevicular fluid cytokine level using intact manufacturer or reused healing abutments: A controlled clinical trial

Protocol summary

Study aim

Comparison of cytokine levels in Peri-implant Crevicular Fluid using intact or reused healing abutments

Design

This study is a phase 3 parallel double-blind clinical trial. 50 qualified individuals will be included in the study. The sampling is done by convenience sampling method. For the first ten percent of the sample size, patients are divided into two study groups by using a coin as the method of distribution. Minimization sampling method will be used to divide the rest of patients into study groups.

Settings and conduct

Place of study: School of dentistry How to do: A double-blind clinical trial Blind Mode: None of the patient and dentist side and data researcher and analyst knows the allocation of groups to individuals.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age over 18 years old; One-stage Implant placement should be performed Exclusion criteria: Smoking; immunosuppressive drugs and antibiotics intake; The presence of periodontal disease.

Intervention groups

Group 1: Intervention with an intact healing abutment
Group II: Intervention with a reused healing abutment

Main outcome variables

IL-1 β and TNF- α cytokine level in the peri-implant crevicular fluid using an intact healing abutment; IL-1 β and TNF- α cytokine level in the peri-implant crevicular fluid using a reused healing abutment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160315027056N2**

Registration date: **2019-08-11, 1398/05/20**

Registration timing: **retrospective**

Last update: **2019-08-11, 1398/05/20**

Update count: **0**

Registration date

2019-08-11, 1398/05/20

Registrant information

Name

Nazila Lashkarizadeh

Name of organization / entity

Kerman university of medical sciences, Dental school

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9021

Email address

n_lashkari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-05, 1398/01/16

Expected recruitment end date

2019-07-07, 1398/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An evaluation to compare peri-implant crevicular fluid cytokine level using intact manufacturer or reused healing abutments: A controlled clinical trial

Public title

peri-implant crevicular fluid cytokine level using healing abutments

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of the patient should be over 18 Implant treatment should be performed in patients with partial or complete edentulous Bone level implant placement in one stage and obtaining suitable primary stability should be possible. Good patient compliance, reference for follow-up visits and observation of post operation instructions should also be possible.

Exclusion criteria:

Patients who have periodontal disease Conditions that affect the immune system such as diabetes and pregnancy The habit of smoking and alcohol or tobacco consumption History of Antibiotics, anti-inflammatory, and immunosuppressive drugs intake three months before the study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **1**

Sampling is done in such a way that two months after the implant placement, the Peri-implant Crevicular fluid from each used or intact healing abutments connected to the implants of each patient is collected in a sample tube. Then the samples will be assessed for cytokine level.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The blinding process is in such a way that the healing abutment connection to implant is done by the corresponding surgeon while the patient is completely unaware of the types of healing abutments. After 2 months, all measurements and peri-implant crevicular fluid sampling from implants are done by one experienced dentist, who is unaware of the types of healing abutments. Based on the patient and implant placement area, a number is assigned to each sampling tube. This way, the person responsible for conducting the ELISA test is also unaware of the types of samples. All clinical measurements are done by the corresponding dentist and are recorded in the patient form by the

dentist assistant. Finally, the gathered information is divided into two groups and presented to the person in charge of performing statistical tests who is unaware of each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Ethics Committee, Vice Chancellor for Research and Technology of University of Medical Sciences Building, First of Ebne Sina Street, Jahad Boulevard, Sommaye Cross road, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Approval date

2019-05-29, 1398/03/08

Ethics committee reference number

IR.KMU.REC.1398.067

Health conditions studied**1****Description of health condition studied**

Peri-implant mucositis

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes**1****Description**

Interleukin-1 β cytokine

Timepoint

Two months after the intervention

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) human kits (HANGZHOU EASTBIOPHARM CO.LTD.) for evaluation of interleukin 1 β levels

2

Description

Tumor Necrotizing Factor α cytokine

Timepoint

Two months after the intervention

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) human kits (HANGZHOU EASTBIOPHARM CO.LTD.) for evaluation of interleukin 1 β levels

Secondary outcomes

1

Description

Plaque Index (Ainamo & Bay 1975)

Timepoint

2 months after the intervention

Method of measurement

Observation in such a way that if the plaque is visible on each of the buccal, lingual, mesial or distal surface of healing abutment 0 code and if it is not visible code 1 is assigned.

2

Description

Bleeding Index (Ainamo & Bay)

Timepoint

2 months after the intervention

Method of measurement

Observation in such a way that if bleeding on probing is visible on each of the buccal, lingual, mesial or distal surface of healing abutment 0 code and if it is not visible code 1 is assigned.

Intervention groups

1

Description

Intervention group: The group in which reused healing abutment (Dio Pars.Co) is attached to the implant.

Category

Treatment - Devices

2

Description

Control group: The group in which intact manufacturer healing abutment is attached to the implant.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman school of dentistry, Periodontology

department

Full name of responsible person

Nazila Lashkarizadeh assistant professor in Periodontology department

Street address

Periodontology department, School of dentistry, End of Shafa street, Jomhoori Eslami Boulevard, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9022

Fax

+98 34 3211 9028

Email

n_lashkari@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Vice Chancellor for Research and Technology of University of Medical Sciences Building, First of Ebne Sina Street, Jihad Boulevard, Sommaye Cross road, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3226 3787

Email

kmu_research@yahoo.com

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, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Nazila Lashkarizadeh

Position

Specialist in periodontics, Assistant professor in periodontics department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Periodontology department, Dental school, End of Shafa street, Jomhoori Eslami Boulevard, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

nazilalashkarizadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Periodontology department, Dental school, End of Shafa street, Jomhoori Eslami Boulevard, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9023

Email

nazilalashkarizadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nazila Lashkarizadeh

Position

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Province

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Postal code

7618759689

Phone

+98 34 3211 9022

Email

nazilashkarizadeh@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The results of the study will be reported without mentioning patient information

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific research centers

Under which criteria data/document could be used

In order to do the same study, or to apply in industry

From where data/document is obtainable

Please email the person responsible for answering nazilalashkarizadeh@yahoo.com

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

In the case of doing researches, the proposal, the reason

for the need for the data and name of the research supporting organization should be sent to the email. If industrial companies are the applicant for the research data they should send the purpose and required

documents for the originality of the company to the email mentioned.

Comments