

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effectiveness of different antimicrobial agents in malodorous prevention in the beginning of prosthetic phase of two-stage implants

Protocol summary

Study aim

Effectiveness of different antimicrobial agents in malodorous prevention in two-stage implants

Design

Current study is a stratified clinical trial (based on gender and age) with equal randomization, controlled, and Triple-blinded which is performed parallel on 51 patients from Implant department of Isfahan University of Medical Sciences. Participants are stratified based on age and gender and randomly assigned to three groups of 17 people. Intervention is done on two of these three groups and the third group is control group.

Settings and conduct

This randomized and Triple-blinded clinical trial is performed on patients who referred to Implant department of Isfahan University of Medical Sciences for surgical exposure of their two-stage implants.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients for whom the two-stage "snow" system is intended (based on expert opinion); gingival depth between 2 and 3 mm No entry conditions: other implant systems; gingival depth too high or too low

Intervention groups

Group 1: 2% Chlorhexidine gel is added to the internal surface of the fixtures. Group 2: 3% Tetracycline ointment is added to the internal surface of the fixtures. Group 3: patients participated in this group are negative controls. No medicine is added to the internal surface of their fixtures.

Main outcome variables

Outcome which is considered to be evaluated in this study is malodorous released after opening the healing abutments. 0: no malodorous 1: hardly smelled malodorous 2: mild malodorous that is easily smelled 3: moderate malodorous 4: severe malodorous 5: intensive malodorous

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210705051795N1**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Amirhossein Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

amir_alty@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of different antimicrobial agents in malodorous prevention in the beginning of prosthetic phase of two-stage implants

Public title

Effect of some antimicrobial agents in malodorous prevention in dental implants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Usage of 2-stage "snow" implant system Gingival depth of 2 to 3 mm

Exclusion criteria:

Uncontrolled systemic disease or history of specific medical condition Smoking habit or use of alcohol Current periodontal disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: 51

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, 51 eligible participants enter the study. These people are categorized individually by "stratified randomization" according to the layers below. Subjects are divided into 2 groups based on gender. Then each group is divided to 3 groups based on age (less than 40, between 40 and 60, more than 60 years old). Eventually we will have 6 groups divided by age and gender. Now members of each group must be equally divided into 3 groups of intervention as following: Names of participants of all 6 groups are written on separate sealed papers. Papers are separated one by one by "drawing lots". The first paper belongs to group 1 of intervention, the second paper belongs to group 2, and the third paper belongs to the control group. This procedure is repeated for all participants of each group and then for all 6 groups. Outcome assessors only attend the malodorous assessment session. They will not know about grouping and the medication used for each patient. (Allocation concealment)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants and therapists (dentists who add the antimicrobial agents into the fixtures in surgery session) will not know how the patients were grouped. Moreover, participants' list and medication used of each will not be shown to the outcome assessors.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical sciences

Street address

Vice Chancellor for Research and Technology-No.4, Hezar Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-07-20, 1400/04/29

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.190

Health conditions studied

1

Description of health condition studied

Malodorous

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The primary consequence variable is the "amount of Malodorous"

Timepoint

Evaluation of Malodorous is performed 3 weeks after the intervention.

Method of measurement

Evaluation is performed based on clinical observation or organoleptic method.

Secondary outcomes

empty

Intervention groups

1

Description

First group of intervention: In the exposure surgery session, before the healing abutments of participants are screwed, 2% Chlorhexidine gel (Morvabon brand; made in Morvabon Company in Iran) is added to the internal surface of implant fixtures applying with a sterile micro-brush.

Category

Prevention

2

Description

Second group of intervention: In the exposure surgery session, before the healing abutments of participants are screwed, 3% Tetracycline ointment (made in Hakim Company in Iran) is added to the internal surface of implant fixtures applying with a sterile micro-brush.

Category

Prevention

3

Description

Control group: For participants of this group exposure surgery is done as usual and no additional intervention is performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Isfahan University of Medical Sciences

Full name of responsible person

Mansour Rismanchian

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Hezar Jerib Ave.

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dentistry@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jerib Ave.

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amirhossein Fathi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Amirhossein Fathi

Position

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amirhossein Fathi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry