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)
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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
Isfehan
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Person responsible for updating data

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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