

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of the effect of metronidazole gel as an adjuvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Protocol summary

Study aim

Determining the effect of metronidazole gel as a complement to mechanical debridement with mechanical debridement alone in the treatment of peri-implantitis.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 32 patients who used a table of random numbers for randomization.

Settings and conduct

at first, after obtaining a written informed consent form from the qualified patients referring to the private practice, after a clinical examination including determining the probing depth and bleeding during probing, if the patient meets the clinical entry criteria, he is referred to a radiologist for a parallel periapical radiograph for Determination of the marginal bone level relative to the implant module crest. In the test group, the sites will be treated with mechanical debridement and then metronidazole gel, and the control group will be treated with mechanical debridement and placebo. No anti-inflammatory or antibiotic drugs should be used after the treatment. Then clinical parameters will be recorded to check the effectiveness of metronidazole gel at the beginning (before mechanical debridement), 1 and 3 months after the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria : - Presence of peri-implantitis disease - No history of peri-implantitis surgical treatment - Patient 18 years and older - Positive BOP - Bone resorption rate > 2mm - Not using antibiotics, mouthwash and periodontal treatment in the last 6 weeks Exit criteria: - Pregnancy - Breastfeeding - Use of anticoagulants - underlying disease (diabetes, kidney disorders, etc.) - smoking

Intervention groups

In the intervention group, the sites will be treated with mechanical debridement and then metronidazole gel.

And in the control group, the sites will be treated with mechanical debridement and then placebo.

Main outcome variables

bleeding on probing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220510054805N2**

Registration date: **2022-12-30, 1401/10/09**

Registration timing: **prospective**

Last update: **2022-12-30, 1401/10/09**

Update count: **0**

Registration date

2022-12-30, 1401/10/09

Registrant information

Name

Azin Khorramdel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3384 0468

Email address

dr.khorramdel@iaut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-18, 1401/12/27

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the effect of metronidazole gel as an adjuvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Public title
The comparison of the effect of metronidazole gel as an adjuvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age greater than or equal to 20 years بیمار مبتلا به پری ایمپلنتایتیس

Exclusion criteria:

pregnancy breastfeeding Taking anticoagulants
underlying disease (diabetes, kidney disorders, etc.)
smoking

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The selection of participants in the study will be done by a simple random method, individually and with a random number table tool. In this way, a number is written in front of the name of each person from the client list, and then a table will be prepared based on the sample size. The selected numbers will be included in the study if they are eligible after the examination. The study will be conducted with a parallel design in which the selection of the desired patient for intervention or control is done randomly with a coin tool. For the patient if it is head, mechanical debridement will be performed along with metronidazole gel, and if it is tails, mechanical debridement will be performed alone.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: will not know whether they are receiving drug or placebo. Researcher and therapist: In terms of packaging, color and consistency, medicinal gel and placebo are completely similar and are named only with letters A and B. Data analyzer: The data is evaluated

numerically without specifying the side with gel and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committees of islamic azad university-
tabriz branch

Street address

Complex No. 2 of Islamic Azad University, Tabriz
branch, To Basmenj, Ahr Tee, Tabriz

City

tabriz

Province

East Azarbaijan

Postal code

5157944533

Approval date

2022-12-13, 1401/09/22

Ethics committee reference number

IR.IAU.TABRIZ.REC.1401.261

Health conditions studied

1

Description of health condition studied

peri-implantitis

ICD-10 code

M27.69

ICD-10 code description

Other endosseous dental implant failure

Primary outcomes

1

Description

Bleeding during probing

Timepoint

Before starting the intervention and 1 and 3 months after
the treatment

Method of measurement

up to 30 seconds after probing, the probed areas are
evaluated and in case of visible bleeding, it is recorded in
the patient's chart and reported as a percentage for each
implant.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after the initial sampling, mechanical debridement and health education, metronidazole gel in the intended injection sites and the clinical parameters of the gums are measured again after 1 and 3 months.

Category

Treatment - Drugs

2

Description

Control group: After the initial sampling, mechanical debridement and health education, placebo in the injection sites and the clinical parameters of the gums are measured again after 1 and 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Third floor, Rush building, It has not reached the telecommunication area, Waliasr

Full name of responsible person

Arash Ghorbanzadeh

Street address

Third floor, Rush building, It has not reached the telecommunication area, Waliasr

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5155673547

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arash7070@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Reza Shaham Far - Assistant Researcher

Street address

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info@iaut.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Azin Khorramdel

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be 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

When the data will become available and for how long

1402

To whom data/document is available

all

Under which criteria data/document could be used

Research

From where data/document is obtainable

dr khorramdel

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

The usual process

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

Islamic Azad University

Full name of responsible person

Azin Khorramdel

Position

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Latest degree

Specialist

Other areas of specialty/work

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