

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effectiveness of complementary antibiotic and standard treatment on oral health-related quality of life in patients with chronic periodontitis

Protocol summary

Study aim

Comparison of the effectiveness of complementary antibiotic and standard treatment on oral health-related quality of life in patients with chronic periodontitis

Design

A randomized controlled clinical trial with a parallel group design of 50 patients, double blinded. Randomization will be done due to the using random numbers table

Settings and conduct

This double-blinded clinical trial will be conducted in Dental School of Isfahan University of Medical Sciences. To ensure complete blindness of patients and surgeons, the drug substance is extracted from Amoxicillin capsules. Empty caps are filled by placebo and they are given to patients in control group in addition to the Placebo of Metronidazole. Caps, tablets and bottles are as the same shape in both of the treatment and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult healthy patients over 18 years with moderate to severe generalized chronic periodontitis; bearing at least 16 teeth in oral cavity. Non-inclusion criteria: Having any other periodontal treatments during the past 6 months; history of allergy to Lidocaine, Amoxicillin and Metronidazole; having Corticosteroid or antibiotic therapy; consuming hormonal drugs and contraceptives; pregnancy in women based on self-expression

Intervention groups

Intervention group: prescription of Amoxicillin 500 mg and Metronidazole 250 mg every 8 hour for 10 days. Control group: Placebo similar to Amoxicillin capsule and Metronidazole tablet

Main outcome variables

Oral health related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201221049786N1**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

Parastoo Parhizkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3439 7916

Email address

parastooparhizkar@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-31, 1399/11/12

Expected recruitment end date

2021-07-14, 1400/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of complementary antibiotic and standard treatment on oral health-related quality of life in patients with chronic periodontitis

Public title

The effect of antibiotic therapy on oral health-related quality of life in patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult healthy patients over 18 years with moderate to severe generalized chronic periodontitis Bearing at least 16 teeth in oral cavity

Exclusion criteria:

Having any other periodontal treatments during the past 6 months History of allergy to Lidocaine, Amoxicillin and Metronidazole Having Corticosteroid or Antibiotic therapy Consuming hormonal drugs and Contraceptives Pregnancy in women based on self-expression

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using the random numbers table. Numbers are read from right side to left side. Even numbers are attributed to treatment group and odd numbers are attributed to the control group. None the patients nor the surgeons will be aware of the randomization results.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial. To ensure complete blindness of patients and surgeons, the drug substance is extracted from Amoxicillin capsules. Empty caps are filled by Placebo and they are given to patients in control group. The Placebo of Metronidazole is also prescribed for patients in control group. The bottles containing the drugs are the same in both of the treatment and control groups.

Placebo

Used

Assignment

Parallel

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

floor 5; No. west-135; Miremaad 4; 24 alley; South Abounaiem street; Kaveh street

City

Isfahan

Province

Isfahan

Postal code

8193843317

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.572

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Oral health related quality of life

Timepoint

Before surgical procedure, 30 and 90 days after antibiotic therapy

Method of measurement

Oral health impact profile(OHIP-14) and Oral impact on daily performance (OIDP) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: prescription of Amoxicillin 500 mg and Metronidazole 250 mg (Daroopakhsh Co. made in Iran) every 8 hour for 10 days

Category

Treatment - Drugs

2**Description**

Control group: Placebo similar to Amoxicillin capsule and Metronidazole tablet (made in Pharmacy School of Isfahan University of Medical Sciences) every 8 hour for 10 days

Category

Placebo

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

Isfahan school of dentistry

Full name of responsible person

Jaber Yaghini

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School of dentistry, Isfahan University of Medical Sciences, Hezarjarib Ave.

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

Esfahan University of Medical Sciences

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

Jaber Yaghini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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

Making all of the information undetectable, cases related to the main outcomes studied and complete filled forms and questionnaires will be available.

When the data will become available and for how long

Start of access from 2022

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Usage of these data for systematic reviews and meta analyses are permitted.

From where data/document is obtainable

To gain any information, please contact with email (parastooparhizkar@ymail.com) or phone number (09387300175).

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

After consultation with officials, the desired files will be sent.

Comments