

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation the effect of adjuvant therapy with ciprofloxacin in non-surgical treatment of sever chronic periodontitis

Protocol summary

Summary

Plan summary Objective: Evaluation the effect of adjuvant therapy with ciprofloxacin in non-surgical treatment of sever chronic periodontitis Plan Execution: Randomized, double-blind, placebo-controlled Inclusion Criteria: Age upper 18 years old 1) Presence of twenty teeth of least 2) 3) Affection with spread mean to severe chronic periodontitis At least (3-5 min clinical attachment loss in more thou 30 percent of the mouth areas. Exclusion criteria: Lack of patient's coloration 1) Antibiotic therapy doing the third past months 2) Allergy background for ciprofloxacin 3) 4) Smoking people or addicted to tobacco 5) Affection with systemic diseases , which are effective on the periodontal conditions such as diabetes , blood disorders and immune system Pregnant women 6) Periodical Intervention Performance during the third past months 7) 8)People who are under treatment with warfarin , antacid T and Cyclosporine. sample volume: 40 in the case group , 40 in the control group Case study: In this double blind clinical trial, 80 patients with chronic periodontitis with a inclusion criteria into the study were equally divided into two groups of case and control. The GBI, PD, CAL indexes in these patients were measured and recorded in the relevant form. Immediately after completing SRP, the patients were randomly assigned to two equal groups of case and control. For the case group, ciprofloxacin 500 mg was given twice daily for 7 days and in the control group placebo capsule with the same dose and timing sequence. Study time: 12 months Primary consequences: GBI,PD,CAL, medicin,time General name of study: The effect of ciprofloxacin in the treatment of severe chronic periodontitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061734582N1**

Registration date: **2017-07-23, 1396/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2017-07-23, 1396/05/01

Registrant information

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Recruitment status
Recruitment complete

Funding source
student

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2017-12-22, 1396/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of adjuvant therapy with ciprofloxacin in non-surgical treatment of sever chronic periodontitis

Public title

Effect of ciprofloxacin on advanced chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria :Age upper 18 years old: Presence of twenty teeth of least: Affection with spread mean to severe chronic periodontitis At least (3-5 min clinical attachment loss in more than 30 percent of the mouth areas . Exclusion criteria: Lack of patient's coloration: Antibiotic therapy during the third past months: Allergy background for ciprofloxacin: Smoking people or addicted to tobacco: Affection with systemic diseases , which are effective on the periodontal conditions such as diabetes , blood disorders and immune system: Pregnant women: Periodical Intervention Performance during the third past months: People who are under treatment with warfarin , antacid T and Cyclosporine.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

This double-blind clinical and placebo-controlled trial is conducted on the patients affected with severe chronic periodontitis referring to the periodontics department of dentistry faculty of Zahedan University of Medical Sciences . the patients , who keep the required conditions are involved into the study if they are satisfied studying the terms . In addition , the consent form is filled by the patient , while the following indexes are measured in these patients and registered in their information form. Gingival bleeding index (GBI): In this method , each tooth is slowly probed in six places using a periodontal probe, mesial , mid and distal are scored on the both of Buccal and lingual surface , while bleeding is scored based on the presence or lack of presence of bleeding , as well the number of bleeding sites (14). Periodontal pocket Depth (PPD) : the distance between sulcus depth to gum margin of the available teeth , pocket depth in the mesiobuccally and dentilingual using Williams periodontal probe will be measured , while fractional measured , while fractional measurements are rounded to the nearest number for one mm. Clinical attachment level : the distance between sulcus depth to CEJ of all the available teeth , CAL in the mesiobuccal

surfaces , midbuccal , Distobuccal, mesio lingual , midlingual , distolingual using Williams periodontal probe (hu-friedly , Chicago . IL ,USA), while the measurements are rounded to the nearest number for one mm. All of the patients will be completely scaled and root surface probed . hygiene training will be given to all of the patients same (tooth brushing , which is done based on the muddied Stallman method in the periodontal patients with reduction , while it will be done based on the basic method in the patients without reduction, as well use of dental floss). Of antimicrobial mouth wash during the study . After completion of SRP , the patients randomly divided in two equal test group and control group using Black randomization method . In this study , the medicine is provided by the plan executor for the researcher , who gives them to the patients while he does not know the delivered medicine type. In this study , two ciprofloxacin antibiotic 500 mg (Dorou pakhsh company) is given to the case group per day for 7 days. While , Darounama capsule (placebo) is prescribed for the control group with same dose and day frequency . In this study , the patient and prescriber have no information about the consumption medicine . After starting the study . the patients refer to evaluate their hygiene status , as well measuring and registering clinical indexes , while they are trained about hygiene . the amount of index plaque of all patients are kept less than 25 percent . based on O'Leary index , However , if the patient involves a problem , will be excluded . these people not collaborate. It must be mentioned that ,all of the data will be registered by the same person

Secondary Ids

empty

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

zahedan university of medical sciences

Street address

zahedan university of medical sciences

City

zahedan

Postal code

-

Approval date

2016-06-05, 1395/03/16

Ethics committee reference number

IR.ZAUMS.REC.1395. 22

2**Ethics committee****Name of ethics committee**

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Postal code

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Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.ZAUMS.REC.1395. 22

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

sever chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis Chronic pericoronitis

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

Gingival bleeding index(GBI)

Timepoint

the first, scnd and fourth months

Method of measurement

bleeding-non bleeding

2**Description**

probing depth(PD)

Timepoint

the first, scnd and fourth months

Method of measurement

Based on Periodontal Probe williams

3**Description**

clinical attachment level(CAL)

Timepoint

the first, scnd and fourth months

Method of measurement

Based on Periodontal Probe williams

4**Description**

Drug

Timepoint

First month for 7 days, two capsules a day

Method of measurement

Based on the presence or absence of consumption

5**Description**

time

Timepoint

the first, scnd and fourth months

Method of measurement

Based on the onset of a therapeutic intervention

Secondary outcomes

empty

Intervention groups**1****Description**

In this study, for the case group, ciprofloxacin 500 milligrams of daroo pakhsh company were given two days daily for 7 days

Category

Treatment - Drugs

2**Description**

In this study, for the control group, placebo 500 milligrams of daroo pakhsh company were given two days daily for 7 days

Category

Treatment - Drugs

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

dentistry zahdan univirsity

Full name of responsible person

student

Street address

dentistry zahdan university

City

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

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Full name of responsible person

dr.hooshang rafighdoost

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City

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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

zahdan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty