Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Name

Elahe Kalvand

Name of organization / entity

Zahdan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 9519

Email address

e.kalvand@zaums.ac.ir

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 thou 30 percent of the mouth areas . Exclusion criteria: Lack of patient’s coloration؛ Antibiotic therapy doing 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 place be-controlled trial is conducted on the patients affected with severe chronic periodontist reoffering 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 it 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 from. 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 Bacall 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 , wile factional measured , wile 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 mesiobuccall surfaces , midbacal , Distobuccall, mesio lingual , midlingual , distolingual using Williams periodontal probe (hu-friedy , Chicago . IL ,USA), wile the mesurments 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 bas 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 ciprofloxine 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 doze 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 , it 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
zahdan university af medical siences
Street address
zahdan university af medical siences
City
zahdan
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
zahedan university of medical siences
Street address
zahedan university of medical siences
City
zahdan

Postal code
-
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, scond and fourth months
Method of measurement
bleeding-non bleeding

2

Description
probing depth(PD)
Timepoint
the first, scond and fourth months
Method of measurement
Based on Periodontal Probe williams

3

Description
clinical attachment level(CAL)
Timepoint
the first, scond 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, scond 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
zahdan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
zahdan university of medical siences
Full name of responsible person
dr.hooshang rafighdoost
Street address
zahdan university of medical siences
City
zahdan
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 siences

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

Contact

Name of organization / entity

dentistry zahdan university

Full name of responsible person

dr.masood bamedi

Position

periodontology

Other areas of specialty/work

Street address

dentistry zahdan university

City

zahdan

Postal code

Phone

+98 54 3342 9519

Fax

Email

e.kalvand@zaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

dentistry zahdan university

Full name of responsible person

dr.masood bamedi

Position

priodontologist

Other areas of specialty/work

Street address

dentistry zahdan university

City

zahdan

Postal code

-

Phone

+98 54 3342 9519

Fax

-

Email

e.kalvand@zaums.ac.ir

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

dentistry zahdan university

Full name of responsible person

elahe kalvand

Position

student

Other areas of specialty/work

Street address

dentistry zahdan university

City

zahdan

Postal code

Phone

+98 54 3342 9519

Fax

Email

e.kalvand@zaumas.ac.ir

Web page address

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