Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of local and systemic Metronidazole as adjunctive treatment in patients suffering from chronic periodontitis

Protocol summary

Study aim
Effects of local and systemic Metronidazole as adjunctive treatment in patients suffering from chronic periodontitis

Design
Phase 3, single-blinded, two arm parallel group randomized trial on 30 patients.

Settings and conduct
30 patients with inclusion criteria who have referred to Alborz Dental Clinic in Urmia or dental office will be randomly divided into three groups. For the the treatment of patients in the first group only Scaling and Root Planing (SRP), in the second group the usual SRP and side treatment in the form of metronidazole tablets in which 20 metronidazole 250 mg tablets every eight hours for a week after mechanical debridement will be prescribed. In the group Third, the usual SRP and side treatment will be prescribed as metronidazole gel. After receiving the standard SRP, 0.75% metronidazole gel will be placed by a non-cutting end syringe inside the 3 pockets included in the study, until the pocket is completely filled. Pocket Probing Depth , Clinical Attachment Level and Bleeding On Probing are assessed at the beginning of the study and 3 months later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients diagnosed with chronic periodontitis with at least three non-adjacent pockets with a probing depth equal to or greater than 4 mm with general health who have not taken any anti-inflammatory drugs or antibiotics in the past six months. Exclusion criteria: To have any allergies to metronidazole or O'Leary plaque index more than 15% after proper oral hygiene training.

Intervention groups
1) The usual treatment of Scaling and root planing (SRP) and side treatment in the form of metronidazole tablets. 2) The usual treatment of Scaling and root planing (SRP) and side treatment in the form of metronidazole gel.

Main outcome variables
Pocket Probing Depth (PPD), Clinical Attachment Level (CAL), Bleeding On Probing (BOP)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210408050898N1**
Registration date: **2021-04-27, 1400/02/07**
Registration timing: **prospective**

Last update: **2021-04-27, 1400/02/07**
Update count: **0**

Registration date
2021-04-27, 1400/02/07

Registrant information

Name
Ehsan Houshyar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3336 3590

Email address
houshyar.e@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-01, 1400/02/11

Expected recruitment end date
2021-08-02, 1400/05/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Effects of local and systemic Metronidazole as adjunctive treatment in patients suffering from chronic periodontitis

Public title

Effects of Metronidazole gel and tablets in gingival disease treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient diagnosed with chronic periodontitis with at least three non-adjacent pockets with probing depth equal to or greater than 4 mm. Patients with systemic health. Patients who have not taken any anti-inflammatory drugs or antibiotics in the last six months. Patients with at least 15 teeth (except third molars) in their mouth. Patients with proper cooperation. Patients who have signed an informed written consent form.

Exclusion criteria:

Patients with medical problems who need antibiotic prophylaxis or treatment intervention. Patients who have had periodontal treatment in the last six months. Patients who have used drugs that affect their periodontal status (such as antibiotics, anti-inflammatory drugs, anticonvulsants, immunosuppressive drugs, and calcium channel blockers) in the last six months. Patients who have undergone orthodontic treatment. Pregnant and lactating patients. Patients with systemic diseases such as diabetes and immunological disorders. O'Leary plaque index more than 15% after proper oral hygiene training. History of Metronidazole allergy.

Age

From **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **3**

خالی

Randomization (investigator's opinion)

Randomized

Randomization description

Patients included in the study will be divided into a control group and two intervention groups based on the pre-generated randomization sequence, which is random and unpredictable. To divide the samples, the block randomization method with the blocks size of 3 and 6 will be used; In this way, by block random number generation software, a random sequence will be generated according to the required sample size for the three groups. First, all the cases in which the three letters A, B, and C can be put together in blocks of 3 and 6 are generated and randomly selected by placing a block between the blocks, and from the layout pattern of that block to patient classification will be used; Then this block will be placed in the main container and we will select another block again. All the blocks of 3 and 6 will be placed in one container. Sealed Envelope software will be used to perform this process.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person reviewing the results of the use of different forms of medication in the participants, as well as the person analyzing the data, do not know the treatment method and the form of medication used in each participant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Ethics committee of Urmia University of Medical Sciences, Urgans Ave, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.UMSU.REC.1399.319

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
Pocket Probing Depth
Timepoint
At the beginning of the study (before the intervention) and three months after the intervention
Method of measurement
Periodontal Probe

2

Description
Clinical Attachment Level
Timepoint
At the beginning of the study (before the intervention) and three months after the intervention
Method of measurement
Periodontal Probe

3

Description
Bleeding On Probing
Timepoint
At the beginning of the study (before the intervention) and three months after the intervention
Method of measurement
Visual

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Receiving of Scaling and Root Planing by ultrasonic cavitron
Category
Treatment - Devices

2

Description
First intervention group: In this group, after Scaling and Root Planing by ultrasonic cavitron ,twenty 250 mg tablets Metronidazole tablets made by Tehran Shimi Company are prescribed every eight hours for a week.
Category
Treatment - Drugs

3

Description
Second intervention group: In this group, after Scaling and Root Planing by ultrasonic cavitron , 0.75% Metronidazole gel made by Pars Daroo Company is placed inside the pockets included in the study until the pocket is completely filled by a syringe with a non-cutting end needle. The gel is reused one week, two weeks and three weeks later.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Dental School
Full name of responsible person
Doctor Ehsan Hooshyar
Street address
Alborz Dental Clinic (Urmia Dental School), Badali Ave , Alborz Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5719736191
Phone
+98 44 3336 3590
Email
houshyar.e@umsu.ac.ir

2

Recruitment center
Name of recruitment center
Dental Office of Periodontology
Full name of responsible person
Doctor Ehsan Hooshyar
Street address
First floor, Milad Noor building, Khanbabakhan, North Khayyam alley
City
Urmia
Province
West Azarbaijan
Postal code
5719157333
Phone
+98 44 3225 3491
Email
houshyar.e@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Doctor Iraj Mohebbi
Street address
Urmia University of Medical Sciences, Urgans Ave, Resalat Blvd

City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3193 7224
Email
dr.mohebbi.iraj@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Ehsan Hooshyar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Alborz Dental Clinic , Badali Ave , Alborz Blvd , Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5719736191
Phone
+98 44 3336 3590
Email
houshyar.e@umsu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Ehsan Hooshyar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Alborz Dental Clinic , Badali Ave , Alborz Blvd , Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5719736191
Phone
+98 44 3336 3590
Email
houshyar.e@umsu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Ehsan Hooshyar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Alborz Dental Clinic , Badali Ave , Alborz Blvd , Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5719736191
Phone
+98 44 3336 3590
Email
houshyar.e@umsu.ac.ir

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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code

Not applicable

Data Dictionary

Not applicable