

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the therapeutic effect of metformin gel in patients with severe chronic periodontitis and control group

Protocol summary

Study aim

The aim of this study is to determine the effect of metformin gel in the treatment of acute severe periodontitis and compare with control group.

Design

Clinical trial with control group, double-blind, randomized

Settings and conduct

Patients referred to the Periodontitis Department of Zahedan School of Dentistry, who have been diagnosed with severe chronic periodontitis a questionnaire containing patient information and inflammatory criteria will be completed by the project manager. Then scaling will be performed for patients and health education for brushing and flossing will be fully explained to all patients. Patients are then referred to the secretary. They randomly select and open one of the 50 closed envelopes, this choice can be metformin gel or placebo. After probing the patient, 3 locations with a CAL greater than 5 mm were selected and the depth of the probe and the CAL are recorded. Then in the selected locations, 10 ml of the drug (metformin gel or placebo) are placed using a Canola needle. The volunteer is then advised to with full caution brush and floss for up to a week in places where medicine is placed. Candidates will be recalled after 3 weeks and 2 months. In the summons, the depth of the probe and the CAL are measured at the drug sites. Then according to the group in which the candidate is located, metformin gel or placebo is applied again to the affected areas. 4 months after the start of the study, in the third session of the call the previous measurements are performed again. The data collected at the beginning of treatment and call sessions are analyzed by statistical methods.

Participants/Inclusion and exclusion criteria

The study included 48 patients diagnosed with severe chronic periodontitis. Patient consent will be obtained from patients.

Intervention groups

Group A metformin gel 1% Group B placebo

Main outcome variables

clinical attachment lost

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047900N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Mohamad Hosein Foroutani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 4004

Email address

mh.forootani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of metformin gel in patients with severe chronic periodontitis and control group

Public title

Investigation of the effect of metformin gel on severe chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Conscious consent of the patient to participate in the research
The depth of the periodontal pocket is greater than or equal to 5 mm
Do not consume alcohol and any tobacco
Do not take antibiotics for three months before the visit
No history of periodontal treatment 6 months before referral
Non-consumption of systemic metformin
Lack of any systemic disease that is effective in a person's periodontal condition.
Not being pregnant or breastfeeding

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is used and 50 closed envelopes are prepared. People randomly select one and open it. Out of 50 envelopes, 25 envelopes will be allocated to Group A placebo and 25 envelopes to Group B 1% metformin gel.

Blinding (investigator's opinion)

Double blinded

Blinding description

Envelopes containing drug codes are kept with the secretary and medicines containing metformin gels and placebo are packaged in similar containers and in groups (A) and (B) are named and coded. The codes for each container are unknown to the patient, the researcher (student) and they will be kept confidential by the supervisor until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr. Hesabi Square, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.ZAUMS.REC.1399.089

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**

Clinical attachment loss

Timepoint

After 3 weeks, 2 months and 4 months after placing the drug deep in the Periodontal pocket

Method of measurement

Through a clinical examination

Secondary outcomes

empty

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

Intervention group: Use of 1% metformin gel

Category

Treatment - Drugs

2

Description

Control group: Using a placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan School of Dentistry, Department of
Periodontology

Full name of responsible person

Mohamad Hosein Foroutni

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Azadegan east St., Zahedan Dental School

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan 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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Sanaz Isar

Position

Bachelor, Research Expert

Latest degree

Bachelor

Other areas of specialty/work

Library and Medical Information

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Position

Dentistry student

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available