

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

#### Street address

Azadegan east St., Zahedan Dental School

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9817699693

#### Phone

+98 54 3244 1814

#### Fax

+98 54 3241 4003

#### Email

mh.forootani@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Mohamad Hosein Foroutani

#### Street address

East Azadegan

#### City

Zahedan

#### Province

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#### Postal code

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#### Phone

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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

#### Street address

East Azadegan

#### City

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#### Province

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+98 54 3341 5705

#### Email

Arbabi.Parvin@zaums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Parvin Arbabi Kalati

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

East Azadegan

#### City

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohamad Hosein Foroutani

**Position**

Dentistry student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

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**Province**

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**Postal code**

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**Phone**

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**Email**

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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