

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of salivary markers (lactate dehydrogenase and hemoglobinA1C) in patients with severe chronic periodontitis before and after phase one periodontal treatment

Protocol summary

Study aim

Determination of LDH and HbA1c levels in patients with severe chronic periodontitis before and after phase one of periodontal treatment

Design

Clinical efficacy without control group and without the need for randomization and Blinding on 30 patients before and after receiving phase 1 periodontal treatment

Settings and conduct

30 person of Clients to the School of Dentistry with entry criteria have selected and after explaining the plan, patients are asked to avoid eating and drinking 2 hours before sampling, then they are asked to spit their saliva in sterile containers (Falcon 15 cc tubes)By spitting method for 2 minutes. and will be tried 3 ml of non-stationary saliva will be collected from each person and this will be done again 1 month after phase 1 of periodontal treatment

Participants/Inclusion and exclusion criteria

inclusion:1- People between 30 and 50 years old 2 - No smoking and other tobacco products 3- Failure to take effective drugs 4- Non-pregnant and non-breastfeeding women 5- consent of the patient 6- Not taking antibiotics in the last 6 months 7- Lack of previous periodontal treatments 8. There are at least 20 teeth in the mouth 9- Do not consume corticosteroids 10. Severe chronic periodontitis 11. Lack of systemic disease affecting periodontal conditions 12. The presence of a larger CAL equals at least two teeth.Exclusion:Patients who do not want to continue working for any reason during the research process or who miss the entry criteria during the research process will be excluded from the study.

Intervention groups

Phase 1 Periodontal treatment for patients with severe chronic periodontitis

Main outcome variables

Lactate dehydrogenase and hemoglobin A1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180122038475N3**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

somaye ansarimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 1814

Email address

ansarimoghadam@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-14, 1399/03/25

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of salivary markers (lactate dehydrogenase and hemoglobinA1C) in patients with severe chronic periodontitis before and after phase one periodontal treatment

Public title

Comparison of lactate dehydrogenase and hemoglobinA1C in patients with severe chronic periodontitis before and after SRP

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

People between 30 and 50 years old Non-pregnant and non-breastfeeding women Conscious consent of the patient There are at least 20 teeth in the mouth Severe chronic periodontitis The presence of a larger CAL is equal to 5 at least two teeth

Exclusion criteria:

Smoking and other tobacco products Taking effective over-the-counter medications Antibiotics have been used for the past 6 months previous periodontal treatment use corticosteroids Existence of systemic disease affecting periodontal conditions

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

ZaUMS Main campus, Jenat Boulevard., Zahedan, Sistan and Baluchestan, Iran

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.ZAUMS.REC.1398.422

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

Lactate dehydrogenase

Timepoint

Periodontal treatment before phase 1 and periodontal treatment 1 month after phase 1

Method of measurement

Laboratory tests of lactate dehydrogenase

2

Description

Hemoglobin A1c

Timepoint

Periodontal treatment before phase 1 and periodontal treatment 1 month after phase 1

Method of measurement

Hemoglobin A1c Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description

Phase 1 Periodontal treatment:scaling and rootplaning

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghadam

Street address

College of dentistry , Eastern Azadegan St. , Zahedan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohammad Bakhshani

Street address

Ethics Committee of Zahedan University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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

Somaye Ansari Moghadam

Position

Assistant Professor of Periodontics Department, Dental College of Zahedan University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghadam

Position

Assistant Professor of Periodontics Department, Dental College of Zahedan University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

hadis abilnajafzadeh

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

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

Statistical Analysis Plan

Not applicable

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