

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of phase I periodontal treatment on the quality of life of patients with moderate to severe periodontitis: a before-after clinical trial

Protocol summary

Study aim

To assess the effect of phase I periodontal treatment on the quality of life of patients with moderate to severe periodontitis

Design

This is a before-after clinical trial, in which 60 eligible patients will be enrolled in the study.

Settings and conduct

The eligible patients with moderate to severe periodontitis referring to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Chronic moderate to severe periodontitis, Moderate to severe gingivitis, CAL equal to or greater than 3 ml, Exclusion criteria: Systemic or metabolic diseases, Indication of surgery, Pregnancy or breastfeeding

Intervention groups

Intervention group: Phase 1 periodontal treatment including scaling and root leveling plus chlorhexidine mouthwash twice a day for a week

Main outcome variables

Primary outcome: Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N370**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of phase I periodontal treatment on the quality of life of patients with moderate to severe periodontitis: a before-after clinical trial

Public title

Effect of phase I periodontal treatment on the quality of life of patients with moderate to severe periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Chronic moderate to severe periodontitis, Moderate to severe gingivitis, CAL equal to

or greater than 3 ml,
Exclusion criteria:
Systemic or metabolic diseases, Indication of surgery,
Pregnancy or breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Hamadan University of Medical
Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.UMSHA.REC.1399.325

Health conditions studied

1

Description of health condition studied

Moderate to severe periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Quality of life

Timepoint

Before the intervention and one week later

Method of measurement

Using Standard Quality of Life (QoL) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Phase 1 periodontal treatment
including scaling and root leveling plus chlorhexidine
mouthwash twice a day for a week

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan city

Full name of responsible person

Dr Maryam Purjebreil

Street address

School of Dentistry, Hamadan University of Medical
Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

dr.purjebreil@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Maryam Purjebreil

Position

Resident of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Hamadan University of Medical
Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

dr.purjebreil@gmail.com

Person responsible for scientific**inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Leila Gholami

Position

Periodontist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Hamadan University of Medical
Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Fax**Email**

l.gholami@hotmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.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

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