

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effects of one-stage full mouth disinfection versus periodontal surgery on oral health-related quality of life in patients with chronic periodontitis

Protocol summary

Summary

Background: Patient-based outcome is an important aspect of periodontal treatments. Information on patients' quality of life after periodontal treatment is limited. Aim: This is a quasi-experimental interventional study aiming at determining the patient perception of oral health and the impact that non-surgical and surgical periodontal therapy have on their quality of life. 40 patients with moderate to advanced chronic periodontitis will be recruited to participate in this study. Subjects are from those who visit a private clinic for the diagnosis and treatment of periodontitis. All the patients sign an informed consent upon entry. At baseline and after non-surgical and surgical treatment, periodontal parameters comprised of pocket depth, clinical attachment level, and bleeding on probing will be recorded by a blind examiner. Periodontal non-surgical treatment is comprised of one-stage full mouth disinfection (Quirynen 1995). Surgical treatment involves quadrant-based open flap debridement with minor osseous surgery. Patients will complete the Iranian version of the Oral Health Impact Profile (OHIP) questionnaire (OHIP-35 after validation), at three stages: baseline, one week post-initial therapy, and after completion of periodontal surgical phase. Data will be analyzed using repeated measure ANOVA, paired and independent t-tests, and Green house-Geisser by SPSS software version 21.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709211081N8**
Registration date: **2017-10-02, 1396/07/10**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Golpar Radafshar

Name of organization / entity

Guilan University of Medical Sciences, School of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 13 1323 0775

Email address

golshad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

This is a self-funding research.

Expected recruitment start date

2017-10-15, 1396/07/23

Expected recruitment end date

2018-08-15, 1397/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of one-stage full mouth disinfection versus periodontal surgery on oral health-related quality of life in patients with chronic periodontitis

Public title

How periodontal treatment affects oral health-related quality of life in patients with chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were a diagnosis of generalized moderate to severe chronic periodontitis and having at least 20 standing teeth. The exclusion criteria were a history of periodontal treatment 6 months prior to entry, taking any medication known to affect periodontal tissues, taking anti-depressant, anti-anxiety, anti-inflammatory, and immunosuppressive medications, uncontrolled diabetes, pregnancy or lactation, smoking, and needing antibiotic prophylaxis.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The original OHIP-49 questionnaire was validated and standardized for Iranian population using CVI and CVR. Some questions did not meet the appropriate CVI or CVR and were deleted. The resultant questionnaire with 35 items was used in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

School of health old building, opposite 17 Shahrivar hospital, Siadati street, Namjoo road

City

Rasht

Postal code

Approval date

2016-01-26, 1394/11/06

Ethics committee reference number

IR.GUMS.REC.1394.395

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

Oral health-related quality of life

Timepoint

Baseline, after non-surgical, after surgical intervention

Method of measurement

Validated Iranian version of the Oral health impact profile questionnaire

Secondary outcomes

1

Description

Periodontal pocket depth

Timepoint

Baseline, after non-surgical, after surgical interventions

Method of measurement

Using a periodontal probe, distance from gingival margin to the base of the pocket is measured

2

Description

Clinical attachment level

Timepoint

Baseline, after non-surgical, after surgical interventions

Method of measurement

Using a periodontal probe, distance from a fix point to the base of pocket is measured

3

Description

Bleeding on probing

Timepoint

Baseline, after non-surgical, after surgical interventions

Method of measurement

Lenox & Kopczyk bleeding index

Intervention groups

1

Description

Non-surgical periodontal treatment based on Quirynen protocol of one stage full mouth disinfection comprised of scaling and root planing with Chx 0.2% pocket irrigation completed within 24 hours.

Category

Treatment - Other

2

Description

Surgery comprised of flap debridement with minor osseous surgery on a quadrant basis over single or multiple treatment episodes, according patient's treatment needs. In case of multiple sessions, a minimum of 2-week interval was considered.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Golpar Radafshar's private clinic

Full name of responsible person

Dr. Golpar Radafshar

Street address

7th floor, Pasteur Medical Building, Golsar intersection

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private clinic, Dr. Golpar Radafshar, associate professor of periodontology, Guilan University of Me

Full name of responsible person

Dr. Golpar Radafshar

Street address

7th floor, Pasteur Medical Building, Golsar Intersection

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Private clinic, Dr. Golpar Radafshar, associate professor of periodontology, Guilan University of Me

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental Sciences Research Center, Dental Faculty, Guilan University of Medical Sciences

Full name of responsible person

Nastaran Mirfarhadi

Position

MS in nursing education

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Periodontology, Dental Faculty, Guilan University of Medical Sciences

Full name of responsible person

Dr. Golpar Radafshar

Position

Associate Professor of periodontology

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Department of Periodontology, Dental Faculty, Guilan University of Medical Sciences

Full name of responsible person

Dr. Golpar Radafshar

Position

Associate professor of periodontology

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty