

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The comparison of the effect of laser therapy versus mouthwash on the oral malodor in patients with chronic periodontitis: a single-blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of laser therapy versus mouthwash on the oral malodor in patients with chronic periodontitis

Design

This is a single-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible 60 patients with chronic periodontitis who will refer to the School of Dentistry during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 50 years Chronic periodontitis with a minimum depth of 5 mm in at least 2 teeth The plaque index less than or equal to 30% Having at least 15 teeth Exclusion criteria: A history of antibiotic use in the last 6 months A history of periodontal surgery A history of digestive or respiratory diseases Oral Fungal Infections Oral lesions, tonsillitis, and adenoid enlargement

Intervention groups

Intervention group: Scrubbing plus Er, Cr: YSGG laser radiation with a wavelength of 2780 nm, MZ5 type, 10 degree angle to the inner surface of the packets, spirally, from bottom to top, for 10-15 min on the first, third and seventh days Control group: Scrubbing plus Halita mouthwash 10 ml after brushing for one min, twice a day, for 7 days

Main outcome variables

Primary outcome: Assessing the oral malodor through physical examination with Rosenberg method in 2 and 12 weeks after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N224**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-16, 1397/03/26**

Update count: **0**

Registration date

2018-06-16, 1397/03/26

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of laser therapy versus mouthwash on the oral malodor in patients with chronic periodontitis: a single-blind randomized clinical trial

Public title

The comparison of the effect of laser therapy versus mouthwash on the oral malodor in patients with chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 50 years Chronic periodontitis with a minimum depth of 5 mm in at least 2 teeth The plaque index less than or equal to 30% Having at least 15 teeth

Exclusion criteria:

A history of antibiotic use in the last 6 months A history of periodontal surgery A history of digestive or respiratory diseases Oral Fungal Infections Oral lesions, tonsillitis, and adenoid enlargement

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single-blind

Placebo

Not used

Assignment

Parallel

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

2018-05-17, 1397/02/27

Ethics committee reference number

IR.UMSHA.REC.1397.94

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

Assessing the oral malodor

Timepoint

2 and 12 weeks after treatment

Method of measurement

Through physical examination with Rosenberg method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Scrubbing plus Er, Cr: YSGG laser radiation with a wavelength of 2780 nm, MZ5 type, 10 degree angle to the inner surface of the packets, spirally, from bottom to top, for 10-15 min on the first, third and seventh days

Category

Treatment - Other

2

Description

Control group: Scrubbing plus Halita mouthwash 10 ml after brushing for one min, twice a day, for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Zahra Lotf Hagh Panah

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

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

Zahra Lotf Hagh Panah

Position

Dental Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Banafsheh Poormoradi

Position

Periodontist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

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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