Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Full name of responsible person
Zahra Lotf Hagh Panah
Position
Dental Student
Latest degree
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Person responsible for updating data

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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