Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of 810 nm Diode LASER with Aphtogel mucoadhesive in the treatment of minor aphthous ulcers of oral mucosa (changes in diameter and pain of aphthous ulcers) in patients with minor aphthous ulcers

Protocol summary

Study aim

Comparison of changes in aphthous wound diameter and spontaneous and functional pain in patients treated with 810 nm Diode LASER and patients treated with Aphthogel mucoadhesive and the effectiveness of two treatments.

Design

Interventional clinical trial with parallel groups, with 2 intervention groups, one-way blind, phase 3 on 50 patients

Settings and conduct

This study will be performed in the clinic of Zanjan Dental School, considering the inclusion and exclusion criteria. One group of patients will receive a LASER beam with a wavelength of 810 nm 3 times a day for 20 seconds at a distance of 10 seconds for 3 days, and the other group will receive the Aphthogel mucoadhesive 4 times a day until recovery. Changes in aphthous ulcer diameter and functional and spontaneous pain in 2 groups will be evaluated in these 3 days.The study will be one-way blind and patients will be given a general explanation of the interventions and will not be given a method superiority over the other.

Participants/Inclusion and exclusion criteria

Patients aged 10 to 80 years with minor aphthous ulcers in the oral mucosa referred to the clinic of Zanjan Dental School without systemic disease prone to aphthous ulcers and non-smokers.

Intervention groups

One group will receive an 810-nanometer Diode LASER beam with a power of 0.5 watts for 3 days, 3 times a day for 20 seconds at a distance of 10 seconds on their aphthous ulcers, and the other group will put the Aphthogel mucoadhesive on their wounds 4 times until they heal.

Main outcome variables

In this clinical study, the effectiveness of two new therapies including Diode LASER and Aphthogel mucoadhesive on minor oral plague wounds is evaluated. The results of this study can help to develop and popularize new treatments for the treatment of oral plague and improve the quality of life of patients with aphthous ulcers in the clinic.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054501N1**
Registration date: **2022-04-25, 1401/02/05**
Registration timing: **prospective**

Last update: **2022-04-25, 1401/02/05**
Update count: **0**

Registration date

2022-04-25, 1401/02/05

Registrant information

Name

Zohre Rahmani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-04-29, 1401/02/09
Expected recruitment end date
2022-06-30, 1401/04/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of 810 nm Diode LASER with Aphtogel mucoadhesive in the treatment of minor aphthous ulcers of oral mucosa (changes in diameter and pain of aphthous ulcers) in patients with minor aphthous ulcers

Public title
Comparison of the effectiveness of LASER with Aphtogel in the treatment of aphthous ulcers of the oral mucosa
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the clinic of Zanjan Dental School who have minor aphthous ulcers of the oral mucosa. Patients should be 10 to 80 years old. Complete the informed consent form by the patient
Exclusion criteria:
Being a smoker Having a systemic disease predisposing to aphthous ulcers
Age
From **10 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are given a general explanation about the intervention methods, but one method is not introduced as superior to the other method and no preference is given to one of the interventions, so patients are blind to the effect of the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
The headquarters of Zanjan University of Medical Sciences, at the beginning of Jomhuri Eslami Boulevard, Azadi Square, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4514685748
Approval date
2022-04-10, 1401/01/21
Ethics committee reference number
IR.ZUMS.REC.1401.020

Health conditions studied

1

Description of health condition studied
Minor aphthous ulcer of the oral mucosa
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The rate of pest diameter changes in the two intervention groups
Timepoint
Measuring the pest diameter on the first, second and third days
Method of measurement
Dental gauge

2

Description
The amount of spontaneous pain in the two intervention groups
Timepoint
Measuring the amount of spontaneous pain on the first, second and third days
Method of measurement
VAS diagram describing the amount of pain

3

Description
The amount of functional pain in the two intervention groups
Timepoint
Measurement of the amount of functional pain in the first, second and third days of lesion
Method of measurement
VAS diagram describing the amount of pain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will be exposed to Diode LASER (elexion) with a wavelength of 810 nm and a power of 0.5 watts in continuous mode with a fiber diameter of 320 µm and a total energy received of 12.9 joules per square centimeter for 3 days, 3 times a day and each time for 20 seconds with an interval of 10 seconds in an area 1.5 cm in diameter around the lesion at a distance of 1 cm from the tip of the fiber from the surface of the pest sores on their wounds.
Category
Treatment - Other

2

Description
Intervention group: This treatment is performed using Aphthogel, which is a mucoadhesive with plant base containing Licorice plant extract. This drug is produced by Exir Danesh Asia Company. The mucoadhesive is packed in the form of 25 adhesives. Each of these adhesives is in the form of a thin layer (less than 1 mm thick) with dimensions of 1 cm2. This mucoadhesive is applied directly to the oral plague.Instructions for using the mucoadhesive (Aphthogel) are explained to the patient as follows : 1. Open the package first. 2. Remove one of the labels and carefully place it on the pest. 3. Moisturize it with saliva, the Aphthogel easily adheres to the pest. 4. The label stays on the pest for 25-30 minutes and then the rest is removed.(Swallowing the drug is not prohibited) 5. Repeat this operation 4 times a day. Use of mucoadhesive continues until complete recovery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Dental School
Full name of responsible person
Robab Noormohammadi
Street address
School of Dentistry, Central Campus of Zanjan University of Medical Sciences, above Ayatollah Mousavi Hospital, Dr. Sobouti Blvd., Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
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School of Dentistry, Central Campus of Zanjan University of Medical Sciences, above Ayatollah Mousavi Hospital, Dr. Sabouti Blvd., Zanjan
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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
Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Robab Noormohammadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared potentially except the data that leads to identifiable individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Any kind of statistical analysis is allowed on the delivered data.
From where data/document is obtainable
Dr Robab Noormohammadi , dr.noormohammadi@zums.ac.ir
What processes are involved for a request to access data/document
The applicant can submit his request via the said email. The requested files will be sent to him as soon as possible.
Comments