

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effectiveness of 810 nm Diode LASER with Aphthogel 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 plaque wounds is evaluated. The results of this study can help to develop and popularize new treatments for the treatment of oral plaque 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3345 7727

##### Email address

zohrezabarjad.1998@gmail.com

##### 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 cm<sup>2</sup>. This mucoadhesive is applied directly to the oral plaque. 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

#### **City**

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#### **Email**

dentist@zums.ac.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Zanjan University of Medical Sciences

##### **Full name of responsible person**

Alireza Shoghli

##### **Street address**

School of Dentistry, Central Campus of Zanjan University of Medical Sciences, above Ayatollah Mousavi Hospital, Dr. Sabouti Blvd., Zanjan

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dentist@zums.ac.ir

#### **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 scientific inquiries****Contact****Name of organization / entity**

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Specialist

**Other areas of specialty/work**

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Robab Noormohammadi

**Position**

Assistant Professor

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**Email**

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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**