Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of low power Nd-YAG laser, Myrtus communis extract and Triadent ointment in the treatment of patients with minor and Major aphthous ulcers referred to the Tabriz faculty of dentistry

Protocol summary

Study aim
Comparison of low power Nd-YAG laser, Myrtus communis extract and Triadent ointment in the treatment of patients with minor and Major aphthous ulcers referred to the Tabriz faculty of dentistry

Design
controlled clinical trial, with three-parallel groups, triple - blind

Settings and conduct
This study will be conducted in the clinics of the University of Medical Sciences and the dental faculty of Tabriz. The random assignment sequence will be determined by a person not involved in the study.

Participants/Inclusion and exclusion criteria
patients with minor and Major aphthous ulcers Being in the first three days of minor and major aphthous ulcers Not taking minor and major anti-aphthous drugs Not having systemic diseases with injuries such as minor and major aphthous Having the necessary cooperation and satisfaction to conduct research Having systemic diseases such as hormonal disorders, anemia, celiac disease, etc. smokers Use of tobacco Pregnancy and breastfeeding

Intervention groups
In this study, laser (wave length, 1064 nm; power, 60 mW; pulse frequency, 1800 Hz; duration, 80 seconds per treatment; dose, 6.3 J/cm2) is used. The laser is placed at a distance of 1 cm from the surface of the lesion and will be moved in a sweeping manner on the surface of the lesion using the long pulse method. The laser is used once. In this study, the patient will use the myrtus communis five times a day until one day after the healing of the lesions. Pour 10 drops of myrtus communis on the cotton and place it on the damaged area for 30 seconds. In this study, Topical intraoral triamcinolone ointment will be used 4 times a day to cover the entire lesion and will continue until the lesion is resolved. duration of drug administration will be based on the instructions of the drug manufacturer.

Main outcome variables
Pain intensity, lesion size, Recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230823059238N3**
Registration date: **2024-03-12, 1402/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-12, 1402/12/22**
Update count: **0**

Registration date
2024-03-12, 1402/12/22

Registrant information

Name
Parya Emamverdizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3335 5965

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-31, 1402/10/10

Expected recruitment end date
2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of low power Nd-YAG laser, Myrtus communis extract and Triadent ointment in the treatment of patients with minor and Major aphthous ulcers referred to the Tabriz faculty of dentistry

Public title

Comparison of low power Nd-YAG laser, Myrtus communis extract and Triadent ointment in the treatment of patients with minor and Major aphthous ulcers referred to the Tabriz faculty of dentistry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with minor and Major aphthous ulcers Being in the first three days of minor and major aphthous ulcers Not taking minor and major anti-aphthous drugs Not having systemic diseases with injuries such as minor and major aphthous Having the necessary cooperation and satisfaction to conduct research

Exclusion criteria:

Having systemic diseases such as hormonal disorders, anemia, celiac disease, etc. smokers Use of tobacco Pregnancy and breastfeeding

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Randomization will be used to randomly select participants. Of course, the patients will be divided into two groups, minor and major, in a simple random manner. Then, each individual group will be assigned to three groups using balanced block randomization. This method of random allocation ensures that the methods of distribution of interventions are balanced. Method of random assignment of participants Stratified Randomization will be used to randomly select participants. First, the patients will be randomly assigned to two minor (30 people) and major (30 people) groups, then each group will be divided into three treatment groups (laser-Myrtus communis and routine) will be allocated. The number of blocks in each floor will be 10 and the volume inside each block will be 3 patients. The order of people entering the study is the sequence within the blocks. This arrangement is done by STATA software version 14. This random allocation method ensures that treatment methods are allocated in a completely balanced way; It also ensures that minor and major patients are distributed in exactly the same number in each of the intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person selecting the research subjects, participants, researchers and data analysts will be unaware of the type of intervention received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

3335 5965

Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.TBZMED.REC.1402.621

Health conditions studied

1

Description of health condition studied

minor and Major aphthous ulcers

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

severity of pain

Timepoint

Before the start of the intervention and 1, 3 and 7 days after the intervention

Method of measurement

The severity of pain will be evaluated through visual analogue scale (VAS)

2

Description

The size of lesions

Timepoint

Before the start of the intervention and 1, 3 and 7 days after the intervention

Method of measurement

The size of the lesions will be measured by placing a transparent graduated grid on the lesion, determining the border of the lesion and replacing the transparent graduated grid on 1 mm graph paper, which is a reliable method for measuring the size of the lesions.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this study, laser (wave length, 1064 nm; power, 60 mW; pulse frequency, 1800 Hz; duration, 80 seconds per treatment; dose, 6.3 J/cm2) is used. The laser is placed at a distance of 1 cm from the surface of the lesion using the long pulse method and will be moved on the surface of the lesion in a sweeping manner. The laser is used once.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this study, the patient will use myrtus communis five times a day until one day after the lesions heal. Pour 10 drops of myrtus communis on the cotton and place it on the damaged area for 30 seconds.

Category

Treatment - Drugs

3

Description

Intervention group 3: In this study, Trident ointment will be used in a group of patients. Topical intraoral triamcinolone ointment will be used 4 times a day to cover the entire lesion and will continue until the lesion is resolved. It should be noted that the duration of drug administration will be based on the instructions of the drug manufacturer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty at Tabriz university of medical sciences

Full name of responsible person

Parya Emamverdizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

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Research department, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Shiva Shahir

Position

Dental Student

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Parya Emamverdizadeh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shiva Shahir

Position

Dental student

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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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