

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

A Comparison Between Pulsed and Continuous CO2 Laser Effect in Recurrent Aphthous Stomatitis and Comparing its Effects with Common Treatment Local Triamcinolone 0.1% : A randomised clinical trial

Protocol summary

Study aim

A Comparison Between Pulsed and Continuous CO2 Laser Effect in Recurrent Aphthous Stomatitis and Comparing its Effect with Common Treatment Local Triamcinolone 0.1%

Design

Two Arm, Parallel, Not Blinded Trial (Postoperative Care and Outcome Assessment). Randomization Was Computerized with Concealed Randomization Sequence Carried Out at an External site.

Settings and conduct

People with Inclusion criteria Who Refer to Urmia University Dental Public Health Ward, Enter to Study After Giving Informed Consent.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: A Reliable History of Minor RAS, Enrollment of the Patient into the Study Within 3 Days or Less of the Appearance of the Ulcers, The Presence of One or More Discrete Minor Aphthous Ulcers
Exclusion Criteria: Pregnancy, Age Less Than 12 Years, Any Known Systemic Disease That could Predispose the Patient to RAS, Treatment of Their Current Ulcers with Any Form of Topical Medications, History of Receiving Any Systemic treatment Known to Have Any Effect on RAS Within the Previous 3 Months

Intervention groups

1) Pulsative CO2 Laser (Ultra Dream Daeshine Enterprise: model: DS40U), 261 Wat Power, Puls Duration: 180 Microsecond, Puls Repeat Time: 40 ms
2) Putting a Layer of the Transparent Gel and Using Continuous CO2 Laser with 1 Wat Power, Radiation Time: 5-10 Second, Spiral Radiation
3) Topical Triamcinolone Acetate 0.1% Ointment, Raha Pharmaceutical Company, 3 Times a Day

Main outcome variables

Ulcer Pain and Severity; Healing Time; Size of the Ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180224038840N1**

Registration date: **2018-03-25, 1397/01/05**

Registration timing: **prospective**

Last update: **2018-06-07, 1397/03/17**

Update count: **1**

Registration date

2018-03-25, 1397/01/05

Registrant information

Name

Seyyed Amir Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3322 4288

Email address

seyedi.a@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-30, 1397/01/10

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

2018-03-30, 1397/01/10

Actual recruitment end date

2018-04-21, 1397/02/01

Trial completion date

empty

Scientific title

A Comparison Between Pulsed and Continuous CO2 Laser Effect in Recurrent Aphthous Stomatitis and Comparing its Effects with Common Treatment Local Triamcinolone 0.1% : A randomised clinical trial

Public title

The Effect of Carbon Dioxide Laser on The Treatment of Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A Reliable History of Minor RAS Enrollment of the Patient into the Study Within 3 Days or Less of the Appearance of the Ulcers The Presence of one or more Discrete Minor Aphthous Ulcers

Exclusion criteria:

Pregnancy Age Less Than 12 Years Any Known Systemic Disease That Could Predispose the Patient to RAS Treatment of Their Current Ulcers with Any Form of Topical Medications History of Receiving Any Systemic Treatment Known to Have Any Effect on RAS Within the Previous 3 Months

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Computerized with Concealed Randomization Sequence Carried Out at an External site.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Alborz Dental Clinic,Alborz Ave.,Urmia Town

City

Urmia

Province

West Azarbaijan

Postal code

5756115111

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

IR.UMSU.Rec.1396.364

Health conditions studied

1

Description of health condition studied

Recurrent Aphthous Stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Ulcer Pain and Severity

Timepoint

Before Intervention,Immediately After Intervention,12,24,48 and 72 h After Intervention

Method of measurement

(VAS) Visual Analogue Scale

2

Description

Healing Time

Timepoint

1,3,5 and 7 Day After Intervention

Method of measurement

Day

3

Description

Size of the Ulcer

Timepoint

1 , 3 , 5 and 7 Day After Intervention

Method of measurement

Millimeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pulsative CO2 Laser(Ultra Dream

Daeshine Enterprise;model:DS40U) ,261 Wat Power,Puls
Duration:180 Microsecond,Puls Repeat Time:40 ms

Category

Treatment - Other

2

Description

Intervention group: Putting a Layer of the Transparent gel and Useing Continuous CO2 Laser with 1 Wat Power,Radiation Time:5-10 Second,Spiral Radiation

Category

Treatment - Other

3

Description

Intervention group: Topical Triamcinolone Acetonide 0.1% Ointment , Raha Pharmaceutical Company, 3 times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Depatment of Oral Medicine,Urmia Dental Shool

Full name of responsible person

Sanaz Partovi

Street address

Alborz Dental Clinic,Alborz Ave,Urmia Town

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Postal code

5756115111

Phone

+98 44 3336 3600

Email

dr.partovi71925@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Seyyed Amir Seyyedi

Street address

Alborz Dental Cilinic,Alborz Ave,Urmia Town

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seyyediamir@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Sanaz Partovi

Position

Dentistry 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

Oroumia University of Medical Sciences

Full name of responsible person

Seyyed Amir Seyyedi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry
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Person responsible for updating data

Contact

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Position
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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on the main consequences can be shared

When the data will become available and for how long

Start the access period from 1398

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Data are available for international researchs

From where data/document is obtainable

Visit urmia university of medical sciences

What processes are involved for a request to access data/document

The data can be accessed only from the oral health department of Urmia Dental School

Comments