Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluating the efficacy of the Er-Cr-YSGG laser before topical corticosteroid therapy in treatment of Oral lichen planus

Protocol summary

Study aim

Determining the efficacy of the Er-Cr-YSGG laser before topical corticosteroid therapy in treatment of Oral lichen planus

Design

Clinical trial with control group, with parallel, double-blind, randomized groups

Settings and conduct

oral lichen planus patients whom are referred to the Department of Oral Patients were interned in this study. The severity of the patient's discomfort from burning for each lesion is measured separately by the analog scale verbal criterion. Using the Thongprasom sign scoring ,is ranking the oral lichen plan lesion on each side from zero to five. The data from this study for each lesion, the time to reach recovery and the amount of VAS before and during the treatment and ranking sessions will be based on the Thongprasom sign scoring standard before the treatment sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: lichen planus Patients with symmetrical two focal parts Exclusion criteria: medications over the past month

Intervention groups

The first group are treated with Tramycinol NN ointment for a maximum of 8 weeks. The whole surface of the lesion is covered with the above ointment three times a day after eating and by the applicator.To blind the patient, a placebo laser is used on the opposite side. the second group before the start of drug treatment with laser radiation (Er.Cr.YSGG) With specifications of American-made Waterlase machine (with 2780 nm parameters, energy: J / cm3 1.75, non-contact pattern, very long pulse, water: 70%, 80%: air, tip MZ 8, 1 mm distance, time 350 microseconds and this radiation in each session, visit is repeated 8 times in 8 consecutive weeks, and the instructions for using medicicin are similar to the first group.

Main outcome variables

The severity of the lesion, burning intensity, the recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200119046187N1**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **retrospective**

Last update: **2020-04-11, 1399/01/23**
Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Gelareh Forouzani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2670 8415

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-09, 1398/08/18

Expected recruitment end date

2020-02-21, 1398/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of the Er-Cr-YSGG laser before topical corticosteroid therapy in treatment of Oral lichen planus

Public title
Laser in lichen planus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lichen planus Patients with symmetrical two focal parts Patient satisfaction and cooperation
Exclusion criteria:
Recurrence history Mucocutaneous involvement Take effective medications over the past month The history of the cancer in the head and neck History of proliferative diseases History of thyroid disease Pregnancy Keratotic lichen planus
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **20**
Samples are taken from patients with oral lichen planus who were referred to the Department of Oral medicine as the faculty of Shahid Beheshti Dental School. The sampling method and calculation of sample size is easy and accessible. The number of samples in each group is 20. There will be 40 samples in total.
Randomization (investigator's opinion)
Randomized
Randomization description
For treatment, symmetrical two focal lesions in the mouth are randomly divided into two groups. Accidental lesions are divided into two groups by permuted random block method as block 4.
Blinding (investigator's opinion)
Double blinded
Blinding description
1. The efficacy of laser is performed by a person other than the collector of the lesion information. 2. The person who is collecting the lesions information does not know in 3. For treatment, symmetrical two focal lesions in the mouth are randomly divided into two groups. Accidental lesions are divided into two groups by permuted random block method as block 4. 4. To blind the patient, a placebo laser is used on the opposite side.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences
Street address
Department of Oral Medicine, Shahid Beheshti Dental School, Daneshjoo Boulevard, Evin, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2019-10-08, 1398/07/16
Ethics committee reference number
IR.SBMU.DRC.REC.1398.166

Health conditions studied

1

Description of health condition studied
Oral lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Oral lichen planus lesions recovery time:time to reach score 1 or zero according to Thongprasom sign scoring in weeks 1 to 8. According to Thongprasom sign scoring in oral lichen planus lesion the score is from zero to five. Zero score: no wounds - Natural mucus, score 1: mild white steria , score 2: white steria with atrophic and erythematous areas (less than 1 cm square), score 3: white steria with atrophic and erythematous areas (more than 1 cm square), score 4: White steria with ulcerative (less than 1 cm square), score 5: White steria with ulcerative (more than 1 cm square)
Timepoint

In each session before treatment, 8 times in 8 consecutive weeks

Method of measurement

By collis and clinical observation

2

Description

The severity of the lesion is based on Thongprasom sign scoring (categories 0 to 5)

Timepoint

In each session before treatment, 8 times in 8 consecutive weeks

Method of measurement

By the collis and clinical observation in each session before the start of treatment in mm / cm (categories 0 to 5)

Secondary outcomes

1

Description

Burning intensity: Verbal Analog scale (score 0 to 10):The patient's severity of discomfort from the burning for each lesion is measured separately by the analog scale verbal criteria, so that the number zero is considered as non-irritating and the number ten is considered as the highest possible burn and the patient is asked to number In this interval, select as the intensity of the burn.

Timepoint

In each session before treatment, 8 times in 8 consecutive weeks

Method of measurement

By determining the number by patients in each session before starting treatment

Intervention groups

1

Description

Intervention group:Before starting drug treatment, this group is under laser radiation (Er.Cr.YSGG) with the specifications of the American Waterlase device (with 2780 nm parameters, energy: J / cm3 1.75, non-contact pattern, very long pulse, water: 70%, 80%: air, tip MZ 8, distance 1 mm, time 350 microseconds and this radiation is repeated 8 times in each session of visit in 8 consecutive weeks and at the same time using topical treatment Triamcinolone None ointment is applied for a maximum of 8 weeks, so that the entire surface of the lesion is covered by the above ointment three times a day after meals.

Category

Treatment - Drugs

2

Description

Control group: Topical treatments are treated with Trimcinolone NN ointment for a maximum of 8 weeks. In such a way that the whole surface of the lesion is smeared with the above ointment three times a day after eating and by the applicator.To blind the patient, a placebo laser is used on the opposite side.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

shahidbeheshty university school of dentistry, oral medicine department

Full name of responsible person

Mehdi Ekhlasmand Kermani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehranchi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid beheshti University of medical science, dental school
Proportion provided by this source
1
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamidreza khalighi
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There are currently plans to release the data.

When the data will become available and for how long

There are currently plans to release the data.

To whom data/document is available

There are currently plans to release the data.

Under which criteria data/document could be used

There are currently plans to release the data.

From where data/document is obtainable

There are currently plans to release the data.

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

There are currently plans to release the data.

Comments