Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Methylprednisolone lozenge to improve symptoms of patient with oral lichen planus: An experimental study and a double-blinded randomized clinical trial

Protocol summary

Study aim

Determining the clinical efficacy of methylprednisolone lozenges in the treatment of oral lichen planus

Design

In this study, in which a phase 3 clinical trial is performed on 40 patients, patients are randomly assigned to methylprednisolone and control groups (20 patients in each group). How to place patients in these two groups is simple random and based on the RAND function of Excel software. This study is double-blind and the physician and patient do not know which group they belong to.

Settings and conduct

The study was performed on 40 patients with oral lichen planus referred to dental clinics in Ahvaz under the supervision of an oral pathologist. Medicines are prepared in uniform containers and patients receive one of the medicine containers based on random numbers. Neither the doctor nor the patient knows the contents of the medicine container.

Participants/Inclusion and exclusion criteria

Inclusion criteria:: 1-Age 18 to 60 years. 2-Willingness to participate in the study and complete the ethical consent form. 3- Women should not be pregnant or breastfeeding. 4- Patients There is no confirmed history of allergic reactions following oral administration of methylprednisolone. Exclusion criteria : 1- Exacerbation of oral lichen planus lesions. 2- Do not use the drug for two consecutive days. 3- allergic reaction to methylprednisolone.

Intervention groups

In the present study, patients will be divided into two groups: Methylprednisolone lozenge group and standard treatment group.

Main outcome variables

The amount of pain and burning Severity of redness and inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053724N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-23, 1401/07/01**
Update count: **0**

Registration date

2022-09-23, 1401/07/01

Registrant information

Name

Mohammadreza Rashidi Nooshabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Methylprednisolone lozenge to improve symptoms of patient with oral lichen planus: An experimental study and a double-blinded randomized clinical trial

Public title
Evaluation of the clinical effect of Methylprednisolone lozenge in oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 60 years Willingness to participate in the study and complete the ethical consent form Women should not be pregnant or lactating Not using allopurinol Not using viral vaccines during treatment Patients do not have a confirmed history of allergic reactions following the oral intake of methylprednisolone The patient does not have a low level of consciousness The patient should not be treated with warfarin The patient does not have an active viral disease

Exclusion criteria:
Aggravation of oral lichen lesions Unwillingness to cooperate during treatment Not using medicine for two consecutive days Emergence of allergic reaction to methylprednisolone

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For blindness, different groups of drugs are placed in uniform and coded containers labeled A or B. In such a way that the physician and the patient do not know the type of medicine in each medicine container. Patients who meet the inclusion criteria receive one of the drugs labeled A or B by a simple randomization method based on the random number function (RAND), of Excel software. Patients will take the drug twice times a day and at the beginning of treatment and after every 2 days for up to 10 days, the status of oral lichen planus lesions will be evaluated.

Blinding (investigator's opinion)
Double blinded

Blinding description
Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container. the drug and the placebo are completely similar in terms of shape, color, smell, and taste.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of JundiShapur Ahvaz University of Medical Sciences

Street address
Ahvaz, Golestan Boulevard, Farvardin St., Shahrivar St., between Bahman and Esfand. No. 147, Unit 5

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Ahvaz

Province
Khouzestan

Postal code
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Approval date
2022-08-20, 1401/05/29

Ethics committee reference number
IR.AJUMS.REC.1401.202

Health conditions studied

1

Description of health condition studied
Oral lichen planus disease

ICD-10 code
L43.8

ICD-10 code description
Other lichen planus

Primary outcomes

1

Description
Redness and inflammation

Timepoint
At the beginning of treatment and after every 2 to 10 days, the status of oral lichen planus lesions is evaluated for the severity of redness and inflammation (score 0 to 4).

Method of measurement
Scoring severe redness and inflammation using a Reeda questionnaire

2

Description

Severe pain and burning

Timepoint

At the beginning of treatment and after every 2 to 10 days, the condition of oral lichen planus lesions is evaluated for the severity of pain and burning (score 0 to 4).

Method of measurement

Scoring Severe pain and burning using VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including 20 patients who are diagnosed with oral lichen planus patients is based on the examination of the patient by a dentist specializing in oral and dental diseases or a biopsy of the tissue of one or more ulcers in the mouth. Patients in the methylprednisolone group, on days 1 to 10, use a lozenge containing 2 mg of methylprednisolone orally twice a day. In this research, methylprednisolone lozenge is prepared using methylprednisolone powder purchased from Caspian Pharmaceutical Company, which has a license from the Food and Drug Organization of Iran, and its safety is checked using standard quantitative and qualitative methods and toxicology.At the beginning of treatment and after every 2 to 10 days, the status of oral lichen planus lesions in terms of pain intensity and irritation (score 0 to 4), and severity of redness and inflammation (score 0 to 4), and the number of lesions were assessed through a questionnaire. Placed.

Category

Treatment - Drugs

2

Description

Control group: includes 20 patients who are diagnosed with oral lichen planus based on the patient's examination by a dentist or oral biopsy of one or more wounds in the mouth. Patients in the control group use topical corticosteroids such as triamcinolone acetonide twice times a day for days 1 to 10, which is considered as the standard and accepted treatment for this disease according to reliable medical sources. At the beginning of treatment and after every 2 to 10 days, the status of oral lichen planus lesions in terms of pain intensity and irritation (score 0 to 4), and severity of redness and inflammation (score 0 to 4), and the number of lesions were assessed through a questionnaire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mohammad Shouryabi Clinic

Full name of responsible person

Mohammad Shouryabi

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Kianpars main street, between second and third west streets, Zarin building, fourth floor, unit 16

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zaker Kish

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Golestan St., Shahrivar St., Esfand St., Ahvaz University of Medical Sciences, Central Library of the Research Vice-Chancellor of the University

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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

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Javad Kushki

Position
University student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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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