Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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

Protocol summary

Study aim

Evaluation of the clinical efficacy of azathioprine in the treatment of oral lichen planus

Design

In this study, in which a phase 3 clinical trial is performed on 50 patients, patients are randomly assigned to azathioprine and control groups (25 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 50 patients with oral lichen planus referred to dental clinics in Yazd 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- Women should not be pregnant or breastfeeding 3- Do not use allopurinol 5- Do not use viral vaccines during treatment 5- Patients There is no confirmed history of allergic reactions following oral administration of azathioprine. Exclusion criteria: 1- Exacerbation of oral lichen planus lesions 2- Do not use the drug for two consecutive days 3- Allergic reaction to azathioprine

Intervention groups

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

Main outcome variables

the pain; Inflammation; Burning; Intensity of redness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N10**
Registration date: **2021-12-21, 1400/09/30**
Registration timing: **prospective**

Last update: **2021-12-21, 1400/09/30**
Update count: **0**

Registration date

2021-12-21, 1400/09/30

Registrant information

Name
Mohsen Zabihi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 35 3820 3865
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-05-14, 1401/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of azathioprine 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 azathioprine lozenge in oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women should not be pregnant or breastfeeding Do not use allopurinol Do not use viral vaccines during treatment Patients do not have a confirmed history of allergic reactions following oral administration of azathioprine 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:
Do not use the drug for two consecutive days Exacerbation of oral lichen planus lesions Allergic reaction to azathioprine

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**

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 three 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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address
Alem sq.

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Yazd

Province
Yazd

Postal code
۸۹۱۶۹۷۸۴۷۷

Approval date
2021-10-27, 1400/08/05

Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.202

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
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

Severe pain and burning using VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 25 patients who are diagnosed with oral lichen planus based on the patient's examination by a dentist or biopsy of the tissue of one or more ulcers in the mouth. Patients in the azathioprine group take lozenges containing 20 mg of azathioprine orally 3 times a day for days 1 to 10. Azathioprine lozenges in this study are prepared using azathioprine powder purchased from Ramofarmine Pharmaceutical Company, which has a license from the Food and Drug Administration of Iran, and its safety toxicity is evaluated using standard quantitative and qualitative methods. 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 25 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 3 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

Dental clinics

Full name of responsible person

Dr. Mohsen Zabihi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Professor

Latest degree

Ph.D.

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