

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of therapeutic effect of Montelukast and Prednisone in patients with oral lichen planus

Protocol summary

Summary

The goal of this study is evaluation of the Montelukast and Prednisone therapeutic effect simultaneously in patients with Oral Lichen Planus (OLP). If this research will be successful, we can reduce corticosteroid dosage, and decrease its side effects. In addition, we can achieve desirable consequences with low adverse effects of Montelukast. Two hundreds patients with erosive oral lichen planus (middle aged males and females) will be selected and diagnosis of all patients will be carried out by clinical sings and biopsy. Inclusion criteria: (1) Diagnosis of OLP will be carried out by clinical history, physical exams and histopathological findings. (2) All of the patients should not use medication for at least two months. (3) They should not have systemic diseases such as diabetes mellitus, hepatitis and trauma history. Exclusion criteria : Patient is non-compliant with treatment until end of study. In this randomized double blinded study (the practitioner and patient do not know the therapeutic process) , the patients divided into two groups randomly ; Group A : daily 20 milligrams (mg) oral Prednisone for 15 days and then 12.5 mg for 15 days and 6.25 mg alternate day for 15 days . Group B : Prednisone similar to group A and 10 mg oral Montelukast daily for first month and then 10 mg Montelukast alternate day for second month. For patients in group A, as well as Prednisone, placebo will be prescribed similar to Montelukast and with same administration. The lesion size with ruler or flexible surgical probe and pain quantity with Visual Analogue Scaling (VAS) will be recorded before treatment and every 2 weeks after treatment for 3 months. Failure of treatment will be defined with lack of clinical improvement for at least three months period. One hundred patients with erosive oral lichen planus (middle aged males and females) will be selected and diagnosis of all patients will be carried out by clinical sings and biopsy. Inclusion criteria: (1) Diagnosis of OLP will be carried out by clinical history, physical exams and

histopathological findings. (2) All of the patients should not use medication for at least two months. (3) They should not have systemic diseases such as diabetes mellitus, hepatitis and trauma history. Exclusion criteria : Patient is non-compliant with treatment until end of study. In this randomized single blinded study (only the practitioner knows the therapeutic process) , the patients divided into two groups randomly ; Group A : daily 20 milligrams (mg) oral Prednisone for 15 days and then 12.5 mg for 15 days and 6.25 mg alternate day for 15 days . Group B : Prednisone similar to group A and 10 mg oral Montelukast daily for first month and then 10 mg Montelukast alternate day for second month. For patients in group A, as well as Prednisone, placebo will be prescribed similar to Montelukast and with same administration. The lesion size with ruler or flexible surgical probe and pain quantity with Visual Analogue Scaling (VAS) will be recorded before treatment and every 2 weeks after treatment for 3 months. Failure of treatment will be defined with lack of clinical improvement for at least three months period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110811389N2**
Registration date: **2012-12-24, 1391/10/04**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-24, 1391/10/04

Registrant information

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Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research of Hamedan University of Medical Sciences

Expected recruitment start date
2013-01-04, 1391/10/15

Expected recruitment end date
2013-03-05, 1391/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effect of Montelukast and Prednison in patients with oral lichen planus

Public title
Therapeutic effect of Montelukast in patients with oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria : (1) Diagnosis of OLP will be carried out by clinical history , physical exams and histopathological findings. (2) All of the patients should not use medication for at least two months. (3) They should not have systemic diseases such as diabetes mellitus, hepatitis and trauma history. Exclusion criteria : Patient is non-compliant with treatment until end of study.

Age
From **40 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

single blinded: only the practitioner knows the therapeutic process . Randomization : Stratified - Blocking

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Vice Chancellor for research , Hamedan University of Medical Sciences , Shahid Fahmideh St. , Hamedan , Iran

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Hamedan

Postal code

65178

Approval date

2012-08-13, 1391/05/23

Ethics committee reference number

D/P/16/35/9/2320

Health conditions studied

1

Description of health condition studied

Lichen Planus

ICD-10 code

L43

ICD-10 code description

Lichen Planus

Primary outcomes

1

Description

Size of lesion

Timepoint

Study onset/after 2,4,6,8,10,12 weeks

Method of measurement

Ruler or flexible surgical probe

2

Description

Pain rate

Timepoint

Study onset/after 2,4,6,8,10,12 weeks

Method of measurement

Visual Analogue Scaling

Secondary outcomes

empty

Intervention groups

1

Description

Montelukast , 10 milligrams oral tablet , first month : daily, one tablet and second month : alternate day, one tablet

Category

Treatment - Drugs

2

Description

Placebo ,10 milligrams oral tablet , similar motelukast , first month : daily , one tablet and second month : alternate day , one tablet

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Dentistry Faculty

Full name of responsible person

Hossein Hasannia

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Dentistry Faculty , Hamedan University of Medical Sciences , Shahid Fahmideh St. , Hamedan , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research , Hamedan University of Medical Sciences

Full name of responsible person

Heydar Tavalani

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Vice Chancellor for Research , Hamedan University of Medical Sciences , Shahid Fahmideh St. , Hamedan , Iran

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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

Vice Chancellor for Research , Hamedan University of

Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan Dentistry Faculty

Full name of responsible person

Hossein Hasannia

Position

Postgraduate Student of Oral Medicine

Other areas of specialty/work

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty