Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of therapeutic effect of Montelukast and Prednison 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 been 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 been 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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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
City
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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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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City
Hamedan
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

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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