Randomised Double Blind Placebo Controlled Trial of the Effect of Oral IMOD in Oral Lichen Planus

Protocol summary

Summary
The objective of this study is to study the effectiveness of oral IMOD in the treatment of Oral Lichen Planus. In this randomized, double blind placebo-controlled trial, 40 patients with diagnosis of oral lichen planus lesion will be recruited. The patients will be randomly assigned into intervention or control groups. The patients in the intervention group will receive IMOD, 120mg capsules, 4 times a day for 3 months. The patients in the control groups will receive placebo with the same dosage. The outcome measures are Pain and burning sensation, Clinical grade of lesion, Oral TNF-α, Clinical Global Impression of Change (CGIC), and Patient Global Impression of Change (PGIC).

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138801191559N2
Registration date: 2010-12-21, 1389/09/30
Registration timing: registered_while_recruiting

Expected recruitment start date
2010-11-22, 1389/09/01
Expected recruitment end date
2011-11-21, 1390/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomised Double Blind Placebo Controlled Trial of the Effect of Oral IMOD in Oral Lichen Planus

Public title
Assessing the effectiveness of IMOD in Oral Lichen Planus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Presence of oral lesions of oral Lichen Planus, Clinical diagnosis of oral lesions: i.e. bilateral or symmetrical reticular lesions with or without atrophic erosive or bolus lesions, Presence of microscopic diagnostic criteria of Lichen Planus: i.e. increase in keratinisation with increase in thickness of granular cell, hydropic degeneration of basal layer, sub-epithelial infiltration of T lymphocytes, no dysplasia), Age 18 - 64
Exclusion criteria: Presence of dysplasia in histopathological view, Presence of lesion close to the amalgam filling, Presence of significant systematic disorder, History of local or systematic therapy during a month prior to the study, Pregnancy or intention of becoming pregnant during the study period (6 months), Breastfeeding, Inability to give informed consent according to the agreed process, Any drug hypersensitivity, Receiving radiotherapy, chemotherapy or any immunosuppressive drug

Age
From 18 years old to 64 years old

Gender
Male

Phase
3

Groups that have been masked

Recruitment status
Recruitment complete

Funding source
Pars Roos Pharmaceutical Company
Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description
Double blinded

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo
Used

Assignment
Parallel

Other design features
The patients will be allocated to the intervention or control group using a separate complete block randomisation method. Blocks of 4 will be used for this purpose. Randomisation will not be exposed to those conducting the study and will be provided in closed letters with successive numbers. The envelope will be opened when a patient is going to join the study.

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Central Building, Ghods St., Keshavarz Blvd., Tehran, Iran
City
Tehran
Country
Iran (Islamic Republic of)
Postal code
Approval date
2010-12-21, 1389/09/30
Ethics committee reference number
1175/130/89/

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
Pain and burning sensation
Timepoint
Baseline and every other week during the first month and every month during the next five month
Method of measurement
Intensity of pain and burning sensation during the previous week will be measured mainly through a 5-point rating numerical scale from no pain to very severe pain.
0 = no pain or burning sensation
1 = mild pain or burning sensation
2 = moderate pain or burning sensation
3 = severe pain or burning sensation
4 = very severe pain or burning sensation

2
Description
Clinical grade of the lesion
Timepoint
Baseline and every other week during the first month and every month during the next five month
Method of measurement
The oral lesions will be clinically graded based on the following grading scale: 0 = normal mucosa without lesion, 1 = reticular lesion with atrophic area less than 1 centimeter, 2 = reticular lesion with atrophic area more than 1 centimeter 3 = reticular lesion with erosive area less than 1 centimeter 4 = reticular lesion with erosive area more than 1 centimeter

Secondary outcomes

1
Description
Level of TNF-α in Saliva
Timepoint
Before and after the intervention
Method of measurement
To measure the TNF-α, the saliva will be collected from the patients without stimulation between 9:00 and 12:00 in the morning. The patients will be asked to pure their saliva in a pot every 60 minutes for 5-15 minutes until the volume reach to at least 2 cc. TNF-α will be measured in the saliva by using ELISA method.

2
Description
Clinical Global Impression of Change (CGIC)
Timepoint
Every other week during the first month and every month during the next five month
Method of measurement
Through a 10-point scale on which the clinician rates the change observed in the patient’s overall status since the beginning of the study.
Patient Global Impression of Change (PGIC)

**Timepoint**
At the end of the treatment

**Method of measurement**
Through a 10-point scale on which patients themselves rate any changes observed in their overall status since the beginning of the study. The scores on this scale varies from “much improved” to “much worse”

**Intervention groups**

1
**Description**
Placebo, 1 capsule every 6 hours, for 3 months

**Category**
Placebo

2
**Description**
IMOD, 120 mg (1 capsule) every 6 hours for 3 months

**Category**
Treatment - Drugs

**Recruitment centers**

1
**Recruitment center**
Special clinic, Faculty of Dentistry, Tehran University of Medical Sciences

**Full name of responsible person**
Dr. Farzaneh Aghahosseini

**Street address**
Faculty of Dentistry, Tehran University of Medical Sciences

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**Country**
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**Sponsors / Funding sources**

1
**Sponsor**
Pars Roos Pharmaceutical Company

**Full name of responsible person**
Dr. Farzamfar

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**Country**
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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
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**Position**
Professor

**Other areas of specialty/work**
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Web page address

Person responsible for updating data

Contact

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