

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Dexamethasone and Cyclosporine , separately and in combination in oral lichen planus

Protocol summary

Summary

The main goal of this study is to determine locally effect of Cyclosporine and Dexametasone seprately and in combination with decreased dosage in oral lichen planuse management and evaluate the side effects. This study is randomized, double blind clinical trial and patients select according to inclusion and exclusion criteria Inclusion criteria ; Patients with oral lichen planus diagnosed according to modified WHO ; Painful lesion (VAS = 3-7) Exclusion criteria Patients with systemic disease :hypertension, pulmonary disease ,kidney disease , severe heart disease , chronic liver disease, uncontrolled diabetes ; pregnant or breast feeding patients and patients who take sterogene based drugs ; Patients who were under local or systemic agents for lichen planus with in two previous months ; Patients with history of cancer and using immunomodulating drugsin last two months ; oral lichen planuse concurrence with skin lesion or other mucosal lesion ; Patients who take beta blockers ,diuretics, anticonvulsants, barbiturates and ACE inhibitors ; Patient with complete denture. Sample size (36)consists of three groups of 12 patients ,Group 1: Dexamethasone 0.1%,Tid,5ml Group2: Cyclosporine 0.1%,Tid,5ml Group3: Dexamethasone 0.05 % + Cyclosporine 0.05 % ,Tid,5ml after oral examinations and recording clinical scoring and visual analogue scale they will be given mouth wash weekly for 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100114713N1**

Registration date: **2013-10-26, 1392/08/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-26, 1392/08/04

Registrant information

Name

Hamed Hossein kazemi

Name of organization / entity

Babol University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Babol university of medical sciences

Expected recruitment start date

2012-10-20, 1391/07/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dexamethasone and Cyclosporine , separately and in combination in oral lichen planus

Public title

locallyl effect of Cyclosporin and Dexamethasone in oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Patients with oral lichen planus diagnosed according to modified WHO criteria ; Painful lesions (VAS = 3-7) Exclusion criteria Patients with systemic disease :hypertension, pulmonary disease ,kidney transparent , heart disease , chronic liver disease, poor controlled diabetes ; pregnancy or breast feeding and patients who take sterogene based drugs ; Patients who were under local or systemic agents for lichen planus in last two months ; Patients with history of cancer and use immunomodulating drugs in last two months ; oral lichen planuse concurrence with skin lesion or other mucosal lesion ; Patients who take beta blockers ,diuretics, anticonvulsants, barbiturates and ACE inhibitors ; Patient with complete denture.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol,Ghanjafrooz avenue ,Babol university of medical science

City

Babol

Postal code

4717641367

Approval date

2013-05-12, 1392/02/22

Ethics committee reference number

2498

Health conditions studied

1

Description of health condition studied

oral lichenplanuse

ICD-10 code

L43

ICD-10 code description

lichen planus

Primary outcomes

1

Description

lesion size

Timepoint

befor intervation, weekly for 6 weeks

Method of measurement

Thongprasom scoring system

2

Description

pain

Timepoint

befor intervation, weekly for 6 weeks

Method of measurement

visual pain score

Secondary outcomes

1

Description

Candidiasis superimposition

Timepoint

weekly for 6 weeks

Method of measurement

culture

2

Description

Telangiectasia

Timepoint

weekly for 6 weeks

Method of measurement

clinical examination

3

Description

atrophy

Timepoint

weekly for 6 weeks

Method of measurement

clinical examination

4

Description

mucosal change

Timepoint

weekly for 6 weeks
Method of measurement
clinical examination

5

Description
taste change
Timepoint
weekly for 6 weeks
Method of measurement
questionnaire form

6

Description
burning sensation
Timepoint
weekly for 6 weeks
Method of measurement
questionnaire form

Intervention groups

1

Description
Group 1: Dexamethasone 0.1%,Tid,5ml,6weeks
Category
Treatment - Drugs

2

Description
Group2: Cyclosporine 0.1%,Tid,5ml,6weeks
Category
Treatment - Drugs

3

Description
Group3: Dexamethasone 0.05 % + Cyclosporine 0.05 %
,Tid,5ml,6weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol University of Medical Sciences
Full name of responsible person
fateme yarmand
Street address
Babol,Ghanjafrroz avenue ,Babol university of
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
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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
Babol 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
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residency student
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Person responsible for scientific 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