Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of cryotherapy and local corticosteroids in the treatment of oral lichen planus lesions

Protocol summary

Summary

Introduction: Oral lichen planus (OLP) is a chronic inflammatory disease of the oral mucosa. The purpose to control the disease is to eliminate pain, ulcer, erythema and to reduce the risk of malignancy. Aim: The aim of this study is to compare the effects of cryotherapy and local corticosteroids in the treatment of oral lichen planus lesions in patients referred to the oral medicine department of Shiraz dental school. Comparing the difference in severity, size and pain reduction of the two treatments are the objectives of this study. Methods: From the patients referred to oral medicine department of Shiraz dental school, 30 patients will be chosen. At the start of treatment each patient will be evaluated by an oral medicine specialist. Inclusion criteria: • Clinical diagnosis of oral lichen planus • Existence of two lesions with similar clinical appearance (with the size difference of less than 1 cm) on the right and left buccal mucosa or right and left side of tongue • Not received any treatment for the lesions for at least 2 weeks ago • Signing the consent form. Exclusion criteria: • Using drugs that are proved to develop lichenoid lesions. • Lesions seen in contact with dental amalgam • Coexisting dermal and genital lesions • Hypersensitivity to drugs being used • Pregnant women • Systemic disease such as systemic lupus erythematosus, erythema multiform, secondary syphilis, graft versus host disease or others systemic disease. From the existing lesions on the right and left side of the buccal mucosa or tongue, one lesion will be chosen randomly for cryotherapy. The chosen lesion will receive one session of 30 seconds cryotherapy with N2O gas. The temperature will be -72°c. For the treatment of the lesion on the other side (control lesion), patients will be instructed to use a triamcinolone acetonide ointment in orabase 3 times daily for 2 weeks. From the third week the use of the ointment will be tapered (2 times daily on week 3, once a day on week 4, alternate day on week 5 and discontinuation on week 6). The patients will be evaluated in a 3 months follow up program (every 2 weeks) from the beginning of the treatment. The lesions will be evaluated in the follow up session by a clinician that is unaware of the type of treatment used for each lesion. (Single blind) Evaluation: In each session the 2 lesions chosen from each patient will be measured by a digital culis. The severity of lesions in each site is based on the form reticular (R), plaque type (P), atrophic (A) and erosive/ulcerative (U) and reported as a sum: Severity of lesion = (R×1) + (P×1.5) + (A×2) + (U×2.5) The efficacy indices (EI) for the evaluation of treatment outcome are recorded in each session: EI = (Severity of lesion before treatment – Severity of lesion in the follow up session) × 100 / Severity of lesion before treatment Pain reduction is measured by the visual analogue scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120311656N1**
Registration date: **2012-12-23, 1391/10/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Maryam Zahed Zahedani

Name of organization / entity

Shiraz University of Medical Sciences, School of Dental Medicine

Country

Iran (Islamic Republic of)

Phone

+98 71 1648 6702

Email address
zahedzm@sums.ac.ir

Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2012-12-20, 1391/09/30
Expected recruitment end date
2013-04-12, 1392/01/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of cryotherapy and local corticosteroids in the treatment of oral lichen planus lesions

Public title
Comparing the effects of cryotherapy and local corticosteroids in the treatment of oral lichen planus lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: • Clinical diagnosis of oral lichen planus • Existence of two lesions with similar clinical appearance (with the size difference of less than 1 cm) on the right and left buccal mucosa or right and left side of tongue • Not received any treatment for the lesions for at least 2 weeks ago • Signing the consent form. Exclusion criteria: • Using drugs that are proved to develop lichenoid lesions. • Lesions seen in contact with dental amalgam • Coexisting dermal and genital lesions • Hypersensitivity to drugs being used • Pregnant women • Systemic disease such as systemic lupus erythematosus, erythema multiform, secondary syphilis, graft versus host disease or others systemic disease.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Zand street
City
Shiraz
Postal code
Approval date
2012-10-04, 1391/07/13
Ethics committee reference number
ct-91-4246

Health conditions studied

1

Description of health condition studied
Oral lichen planus
ICD-10 code
L43
ICD-10 code description

Primary outcomes

1

Description
Reduction in severity of lesions
Timepoint
2 weeks after treatment
Method of measurement
cilinical judgement of a capable cilinician

2

Description
lesion size
Timepoint
2, 4, 6, 8, 10, 12 weeks after treatment
Method of measurement
with a digital culis

3

Description
Pain
Timepoint
2, 4, 6, 8, 10, 12 weeks after treatment
Method of measurement

Visual analogue score

Secondary outcomes

1

Description
Patient satisfaction of each individual treatment
Timepoint
3 months after treatment
Method of measurement
by asking the patient to give a percentage of satisfaction for each side

Intervention groups

1

Description
Control Group: Topical corticosteroid in orabase
Category
Treatment - Drugs

2

Description
Intervention: Cryotherapy with N2O gass
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Dental school
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ŝhiraz University of Medical Sciences
Full name of responsible person
Dr. Pustforoosh
Street address
Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ŝhiraz 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
Shiraz University of Medical Sciences, Dental school
Full name of responsible person
Dr. Maryam Zahed
Position
Resident of Oral Medicine
Other areas of specialty/work
Street address
ghasrodasht, Ghomabad, Shiraz Dental School
City
Shiraz
Postal code
Phone
+98 71 1648 6702
Fax
Email
maryamzhd@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences, Dental school
Full name of responsible person
Dr. Dariush Amanat
Position
Associate Professor
Other areas of specialty/work
Street address
Ghasrodasht, Ghomabad, Shiraz Dental School
City
Shiraz
Postal code
Phone
+98 71 1628 6777
Fax
Email
amanatd@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr Maryam Zahed

Position

Resident

Other areas of specialty/work

Street address

City

Shiraz

Postal code

Phone

00

Fax

Email

maryamzhd@yahoo.com

Web page address

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