

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison the efficacy of bovine colostrum with topical triamcinolone acetonide 0/1% in the treatment of erosive oral lichen planus.

Protocol summary

Summary

Oral lichen planus (OLP) is a common oral mucous autoimmune disease with unknown etiology. The most commonly used topical and systemic therapies including corticosteroid is triamcinolone. Since long-term use of systemic corticosteroids have many side effects (including suppression of the immune system, increase their osteoporosis and fractures). In this study, it became that of bovine colostrum include growth factors, antimicrobial and immune factors (such as INF- γ , IL-6, IL-1 β , etc.) and its beneficial effects on OLP and other immunological diseases has been demonstrated in case reports on the erosive OLP lesions we studied. Designing: Phase 2 randomized double-blind, without placebo-controlled trials. Inclusion criteria: patients with erosive oral lichen planus. Exclusion criteria: taking any medication lichenoid; any other oral lesions (such as Lichenoid reaction). Sample size: 40. Methods: this is a bovine Colostrum are provided to patients. (4 times a day and each time for 2 min, 5 ml in the mouth gargle). Also, patients treated with triamcinolone acetonide is also called the drug four times daily for 4 weeks and the lesion can be localized and 10 minutes after taking both drugs, avoid the eating and drinking and brushing. All patients refer to again after two weeks and four weeks after treatment to evaluate the lesion and the final questionnaire are presented. Clinical evaluation of measuring the extent of the lesion by lesion graded paper using a ruler to measure 100 mm segmentation is done. Pain and burn patients who are determined by the VAS scale is done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109197594N1**

Registration date: **2012-09-04, 1391/06/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-04, 1391/06/14

Registrant information

Name

Mohammadreza Ebrahimpour

Name of organization / entity

School of Dentistry, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tehran University of Medical Sciences

Expected recruitment start date

2012-10-21, 1391/07/30

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of bovine colostrum with topical triamcinolone acetonide 0/1% in the treatment of erosive oral lichen planus.

Public title

comparison the efficacy of bovine colostrum with topical

triamcinolone acetonide 0/1%

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with erosive oral lichen planus; lack of effective systemic drugs for at least three months of oral lichen planus and lack of effective topical medications for at least a month of oral lichen planus.

Exclusion criteria: systemic disease; taking any medication lichenoid and consumption of any tobacco.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

سامانه پژوهشبار دانشگاه علوم پزشکی تهران

Secondary trial Id

90-04-69-14575

Registration date

1390-04-17, 773/01-1432

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran - Qods Avenue - Education Building of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-07-03, 1391/04/13

Ethics committee reference number

90-4-69-14575-59013

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

Clinical extent of the lesion

Timepoint

Before Intervention- after two weeks Intervention -after four weeks Intervention

Method of measurement

Ruler (per square millimeter)

Secondary outcomes

1

Description

Pain

Timepoint

Before Intervention- after two weeks Intervention -after four weeks Intervention

Method of measurement

According to statements made by the patient (by scale VAS)

2

Description

Burning sensation

Timepoint

Before Intervention- after two weeks Intervention -after four weeks Intervention

Method of measurement

According to statements made by the patient (by scale VAS)

Intervention groups

1

Description

Intervention group: Five ml of pasteurized bovine colostrum under standard conditions between patients in the distribution of sterile vial and instructions for its use, both in writing and orally to patients placed.(4 times a day and each time for 2 min, 5 ml in the mouth gargle). Meanwhile, 10 minutes after taking drug,avoid the eating and drinking, and brushing.All patients refer again after two weeks and four weeks after treatment to evaluate the lesion and to complete the final questionnaire

Category

Treatment - Drugs

2**Description**

control group: This group of patients treated with triamcinolone acetonide is also called the drug four times daily for 4 weeks and the lesion can be localized. Meanwhile, 10 minutes after taking drug, avoid the eating and drinking, and brushing. All patients refer again after two weeks and four weeks after treatment to evaluate the lesion and to complete the final questionnaire.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Oral Diagnosis, Dental School, Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Tehran 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**

School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Ebrahimpour

Position

Final year PhD student at the General Dental

Other areas of specialty/work**Street address**

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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