

# 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- $\gamma$ , IL-6, IL-1 $\beta$ , 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)

###### Phone

+98 31 1229 8247

###### 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**

Mohammadreza Ebrahimpour

**Street address**

iran

**City**

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

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**Full name of responsible person**

Miss. Alamdar

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**City**

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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

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Mouth disease specialist

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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*