Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-1β, 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 lichenoied; 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
ali_e66110@yahoo.com

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 lichenoied 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 پژوهشیار 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
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Miss.Alamdar

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

City
Tehran

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
Amir Abad Street, North End - after the Atomic Energy - Faculty of Dentistry Tehran University of Medical Sciences

City
Tehran

Postal code

Phone
+98 913 329 1873

Fax

Email
ali_e66110@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person
Dr. Mahnaz Sahebjamie

Position
Mouth disease specialist

Other areas of specialty/work

Street address
Amir Abad Street, North End - after the Atomic Energy - Faculty of Dentistry Tehran University of Medical Sciences

City
Tehran

Postal code

Phone
+98 912 306 3270

Fax

Email
sahebjam@sina.tums.ac.ir

Web page address

Person responsible for updating data

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
Amir Abad Street, North End - after the Atomic Energy - Faculty of Dentistry Tehran University of Medical Sciences
City
Tehran
Postal code
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+98 913 329 1873
Fax
Email
ali_e66110@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