

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of Effectiveness of Combination Nano micelle Curcumin Gel %1 with Triamcinolone Acetonide Mouthwash %0.1 in Oral Lichen planus

Protocol summary

Study aim

تعیین میزان تاثیر مصرف توام ژل نانومیسل کورکومین 1% و دهانشویه تریامسینولون استوناید 0.1% در لیکن پلان دهانی

Design

Randomised, parallel group trial with blinded outcome assessment

Settings and conduct

This study be doing on patient with oral lichen planus who referred to Oral medicin Department of shahid Beheshti university. In one group ,Nanocurcumin gel with triamcinolone mouthwash and another group placebo gel with triamcinolon mouthwash prescribed for one mouth..Gels with same coulure and shap gave to the patients. Rsercher and patient dont aware type of drugs. Clinically evalution and assessment lesions of patient doing with one persion.

Participants/Inclusion and exclusion criteria

All patient has typically Lichen Planus symptomatic(erosive-atrophic) symptoms such as soreness and burning sensation Inclusion criteria for axceptance of this study excistance of vickham sria and for the case difficulty for diagnose were doing histopathologig assessment .patient don't therapy with topical corticostroid within 2 weeks ago and dont use systemic corticostroid within one month ago and dont use of analgesic

Intervention groups

Group A reciving nanocurcumin gel%1 and triamcinolone acetomid mouthwash %0.1 and Group B reciving with triamcinolone acetomid mouth wash%0.1 and gel placebo. patient aqueous mouthwash for 1 minute ,3 times a day for one mouth. After use of mouthwash patient apply the gel in the lesion of the mouth. This protocol was described to the patient.

Main outcome variables

Oral lesions, recovery rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190523043678N1**

Registration date: **2019-06-11, 1398/03/21**

Registration timing: **retrospective**

Last update: **2019-06-11, 1398/03/21**

Update count: **0**

Registration date

2019-06-11, 1398/03/21

Registrant information

Name

Shahzad Gholami hasanabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7704 0184

Email address

shahzad.kf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-17, 1397/07/25

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

2018-11-16, 1397/08/25

Actual recruitment end date

2019-05-05, 1398/02/15

Trial completion date

2019-05-05, 1398/02/15

Scientific title

Evaluation of Effectiveness of Combination Nano micelle Curcumin Gel %1with Triamcinolone Acetonide Mouthwash%0.1 in Oral Lichen planus

Public title

Evaluation of Combination Nano micelle Curcumin with Triamcinolone Acetonide in Oral Lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with sympathetic lichen planus (erosive or atrophic) with burning or pain Clinical diagnosis (Wicham lines) and in cases where it was difficult to achieve a definitive diagnosis of the lesion, a histopathologic evaluation was used The patient has not been taking topical corticosteroid therapy over the past two weeks, he has not used systemic corticosteroids during the past month. The patient has not used Analgesic and anestheticpain

Exclusion criteria:

Patients with lichenoid lesions caused by drugs or dental materials pregnant or lactation Patients who have other lesions similar to systemic leukoplakia and systemic lupus in conjunction with lichen planus Historh of malignancy Non-cooperative patients and patients who do not take medication

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Four blocks are considered as two assignments for the intervention group and two allocations for the control group. Six possible modes of permutation of treatments are listed, and each one is written on a card. Each time a block is selected among them, and the order in the block is to be marked to allocate treatment for all 50 (12 blocks). Randomization is done by a design specialist. Hiding is done through the main investigator. On each of the 30 cards, we write a sequence of sequences and put them in sealed envelopes. The envelopes are placed in the box, respectively. For participants, the order of entry of one of the envelopes is allocated respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Curcumin gel and placebo gel are given in tubes of a shape and color to patients. In this study, the

investigator and patient do not know the type of drugs (double blind) Examination of patients and evaluation of oral lesions before and after oral administration by one person.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Shahid Beheshti University of Medical sciences.

Street address

Schoole of Dentistry:Daneshjoo BLVD,Tabnak st,Chamran Highway,Tehran ,Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2018-10-14, 1397/07/22

Ethics committee reference number

IR.SBMU.DRC.REC.1397.014

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

Severity and size of the lesion

Timepoint

Base Day (0), Day 14, Day 28

Method of measurement

with a scaled abslang

2

Description

Reduction in severity of lessions

Timepoint

Base Day (0), Day 14, Day 28

Method of measurement

Efficacy Index

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In this group, patients receiving 1% Nanocorcinem gel with triamcinolone mouthwash receive one-tenth of a percent for three weekly doses per week. (Half an hour after each meal, use a medication and use it for half an hour after eating and drinking). After using mouthwash for 5 minutes, the gel should be swallowed. This instruction is explained to all patients.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients receiving placebo gel and triamcinolone mouthwash receive one-tenth of a percent for use at weekly intervals three times a day. (Half an hour after each meal, use a medication and use it for half an hour after eating and drinking). After using mouthwash for 5 minutes, the gel should be swallowed. This instruction is explained to all patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry of Shahid Beheshti University of Medical sciences

Full name of responsible person

Shahzad Gholami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehranchi

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahzad Gholami

Position

Resident of Oral medicine

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected data will be shared after deidentification of participants

When the data will become available and for how long

6 month after publication data will become available

To whom data/document is available

The researchers in academic institutions

Under which criteria data/document could be used

The researchers in academic institutions

From where data/document is obtainable

The researchers in academic institutions can email responsible person and request information

What processes are involved for a request to access data/document

The researchers in academic institutions can email responsible person and request information

Comments