Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Effectiveness of Combination Nano micelle Curcumin Gel %1with 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 استونايد .01%در لیکن پلان دهانی

Design

Randomised,parallel group trial with blined 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 typicaly Lichen Planus symptomatic(erosive-atrophic) symptoms such as soreness and burning sensation Inclusion criteria for axceptance of this study excistance of vickham sreria and for the case difficulty for diagnose were doing histopathologig assessment .patient don’t therapy with topical corticostreroid within 2 weeks ago and dont use systemic corticostroid within one mounth ago and dont use of analgesic

Intervention groups

Group A reciving nanocurcumin gel%1 and triamcinolone acetonid mouthwash %0.1 and Group B reciving with triamcinolone aceetonid mouth wash%0.1 and gel placebo.patient aqueous mouthwash for 1 minute ,3 times a day for one mounth.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
Thehran

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 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 willbe shared after deidentification of participants
When the data will become available and for how long
6 mounth 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