Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of betamethasone niosomal mouthwash with non-niosomal form in treatment of oral lichen planus patients

Protocol summary

Study aim
Determining the effect of niosomal mouthwash compared to non-niosomal betamethasone in oral lichen planus patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. The randomization sequence is performed using a random number generator in Microsoft Excel.

Settings and conduct
Faculty of Dentistry, Kerman University of Medical Sciences Confirmation of lichen planus disease by a specialist in oral and dental diseases Blocked randomization (block size six) Demographic characteristics of patients, type of treatment received, pain intensity with visual analog scale (VAS) and appearance score with Thongprasom criteria with 0-5 classification will be recorded. Patients will receive betamethasone mouthwash treatment in two fully blind groups in niosomal and non-niusomal form together with V-One mouthwash for four weeks and they will be asked to consume it three times a day after eating and brushing their teeth. .

Participants/Inclusion and exclusion criteria
Entry criteria: including ulcerative or atrophic lichen planus Exclusion criteria: pregnancy; breastfeeding; current use of anticoagulants or antiplatelet drugs; current orthodontic treatment; history of gastric ulcer; duodenum ulcer; gallstones, liver diseases, any malignancy or viral infection in the mouth, no history of treatment Topical for OLP in the past two weeks or any systemic treatment for OLP in the past four weeks.

Intervention groups
Control group: Treatment of patients with lichen planus with non-nizosomal betamethasone mouthwash three times a day for four weeks. Intervention group: Treatment of patients with lichen planus with niosomal betamethasone mouthwash three times a day for four weeks.

Main outcome variables
Determining the effect of niosomal mouthwash compared to non-niosomal betamethasone in oral lichen planus patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240804062631N1**
Registration date: **2024-08-22, 1403/06/01**
Registration timing: **prospective**

Last update: **2024-08-22, 1403/06/01**
Update count: **0**

Registration date
2024-08-22, 1403/06/01

Registrant information
Name
Sina Kakooei
Name of organization / entity
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Iran (Islamic Republic of)
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+98 34 3211 3736
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-10, 1403/06/20
Expected recruitment end date
2024-11-10, 1403/08/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of betamethasone niosomal mouthwash with non-niosomal form in treatment of oral lichen planus patients

Public title
Betamethasone mouthwash in the treatment of patients with oral lichen planus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Includes ulcerative or atrophic lichen planus that is clinically or histopathologically confirmed
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used to allocate people to study groups. For this, a sequence of 13 letters A, B is produced and people are assigned to study groups in the order of the letters in the generated sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines will be given to the participants completely blindly by the final year dental student. Both participants and investigators will be blinded to treatment assignment. All patients are also given Ve Wan mouthwash. Block randomization will be used to allocate people to study groups. For this, a sequence of 13 letters A, B is produced and people are assigned to study groups in the order of the letters in the generated sequence.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Jahad Ave
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2024-08-04, 1403/05/14
Ethics committee reference number
IR.KMU.REC.1403.185

Health conditions studied

1

Description of health condition studied
lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Determining the average recovery period and the size of oral ulcers in oral lichen planus patients in 2 study groups
Timepoint
Determining the average healing period and the size of oral ulcers in oral lichen planus patients in 2 study groups before and after the intervention.
Method of measurement
Visual analog scale

2

Description
Determining the investigated parameters in the wound in 2 studied groups
Timepoint
Determining the investigated parameters in the wound on days 1 to 8 in 2 studied groups
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: People with lichen planus treated with Niosomal betamethasone mouthwash, three times a day for 4 hours.
Category
Treatment - Drugs

2

Description
Control group: People with lichen planus treated with Non-niosomal betamethasone mouthwash, three times a day for 4 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and Dental Diseases Research Center
Full name of responsible person
Sina kakooei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Sina Kakooei
Position
Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Participant data file, part of the data such as information related to the main outcome
When the data will become available and for how long
6 months after completing the study
To whom data/document is available
The data is published in the form of articles.
Under which criteria data/document could be used
The use of the information of this study is unimpeded if the published article is cited
From where data/document is obtainable
Sina Kakooei 09131976427 kakooei.s@gmail.com
What processes are involved for a request to access data/document
Documentation after printing the article through
Available from the corresponding author.
Comments