Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Formulation and standardization of mucoadhesive form of Golnar (Punica granatum L.) and its effectiveness in erythematous and erosive lesions of oral lichen planus and its comparison with mucoadhesive form of triamcinolone: a randomized double-blind clinical trial

Protocol summary

Study aim

Determining the effecacy of Golnar mocuadhesive on erythematous and erosive lesions of OLP

Design

Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct

Informed consent is obtained from the patients. Patients are randomly divided into two groups: The first group is the control group, which includes 20 patients who receive triamcinolone mucoadhesive form 3 times a day. The second group, the intervention group, includes 20 patients who receive the form of mucoadhesive containing Golnar 3 times a day. Patients receive the medicine every two weeks to one month. Visits to check the symptoms of OLP are performed until the end of the second month. It will be explained to the patients used an amount that covers a thin layer onthe lesion. Nystatin drops will be prescribed to both groups. The place of study is a private office specializing in oral and maxillofacial diseases.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Existence of clinical criteria and pathology of erythematous and erosive lesions of OLP Non-entry criteria: -Patients with a history of chronic diseases - Active viral disease in the oral cavity -Patients with a history of allergy to herbal medicines -Received local treatments during the last 2 weeks or systemic treatments during the last 4 weeks for lesions of OLP

Intervention groups

Intervention group: including 31 patients who receive the form of glue containing Gelnar 3 times a day. Control group: including 31 patients who receive triamcinolone 0.1% mucoadhesive form 3 times a day.

Main outcome variables

Formulation and standardization of mocuadhesive containing golnar (Punica granatum L.) and determining its effecacy in erythematous and erosive lesions of OLP and comparing it with the mocuadhesive form of triamcinolone during a randomized double-blind clinical study

General information

Reason for update

با توجه به شیوع پایین بیماری لیکن پلان دهانی و متعاقب آن شیوع کمتر ضایعات اروزیو، و با در نظر گرفتن محدودیت‌های موجود در دسترسی به بیماران واجد شرایط و همچنین مرور مطالعات و مقالات پیشین انجام‌شده در این زمینه، حجم نمونه مطالعه حاضر ۴۰ نفر تعیین گردید.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240212060964N1**
Registration date: **2024-03-06, 1402/12/16**
Registration timing: **prospective**

Last update: **2025-12-28, 1404/10/07**
Update count: **1**

Registration date

2024-03-06, 1402/12/16

Registrant information

Name

Seyede Zahra Moravej

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4535

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2026-09-22, 1405/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation and standardization of mucoadhesive form of Golnar (Punica granatum L.) and its effectiveness in erythematous and erosive lesions of oral lichen planus and its comparison with mucoadhesive form of triamcinolone: a randomized double-blind clinical trial

Public title
The effectiveness of Pomegranate flower on oral lichen lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of clinical criteria and pathology of erythematous and erosive lesions of oral lichen planus
Exclusion criteria:
Patients with a history of chronic diseases such as hypertension, diabetes, etc. Active viral disease in the oral mucosa Patients with a history of allergy to herbal medicines-receiving local treatment in the last 2 weeks or systemic treatment in the last 4 weeks for lesions of oral lichen planus
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method will be used using blocks of 4. A person who is not involved in the process of taking patients and evaluating patients will create a random sequence using the site: https://www.sealedenvelope.com And based on the sample size, 15 blocks of 4 will be created. Each patient will be given a unique code that can be created on this site. Therefore, the concealment is observed and the patients and people involved in the study do not know in which group the next person will be placed and they will not know about the random sequence and only the statistics consultant will know about the random sequence and the codes will remain with them.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines and placebo are in similar containers with the same shape, color and smell. Specific codes are inserted by a third person on the label of the medicine box and placebo. Patients and researchers do not know the concept of codes.؛
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Ethics Committee
Street address
6th floor, Central Organization of Tehran University of Medical Sciences, corner of Qods St, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2024-02-07, 1402/11/18
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.169

Health conditions studied

1

Description of health condition studied
Erythematous and erosive lesions of oral lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
- Determining the formulation of the adhesive mucus form containing Golnar- Determining the pH of the form of glue containing Golnar- Determining the release of the

extract from the adhesive mucus ointment containing Golnar- Determining the amount of adhesiveness of the adhesive mucus form containing Golnar- Determining the rheological properties of the form of glue containing Golnar- Determining the microbial stability of the adhesive mucus form containing Golnar- Comparison of the average pain score of lichen planus between two groups of adhesive mucus form containing Golnar and triamcinolone adhesive form- Comparison of the average lichen plan score between the two groups of adhesive mucus form containing Golnar and triamcinolone adhesive mucus- Comparison of the frequency of lichen planus lesions between the two groups of adhesive mucus form containing golnar and triamcinolone adhesive mucus- Comparison of the average score of response to lichen planus treatment between two groups of adhesive mucus form containing Golnar and triamcinolone adhesive mucus- Comparison of the average duration of treatment of lichen planus between two groups of adhesive mucus form containing Golnar and triamcinolone adhesive mucus- Comparison of the average Lichen Plan pain score within each group before and after treatment- Comparison of the average score of Lichen Plan within each group before and after treatment- Comparison of the frequency of lichen planus lesions in each group before and after treatment- Comparison of the mean response score to lichen planus treatment within each group before and after treatment

Timepoint

The beginning of the study, 2, 4, 6 and 8 weeks after the start of the study

Method of measurement

- Pain ruler or Visual Analog Scale (VAS): A scaled page from 0 to 10 is given to the patients and according to the pain intensity of the lesions, a numerical score between 0 (in the absence of pain) and 10 (the most severe) is given.- The largest diameter of each lesion is measured by a specialist using calipers and (or dental floss for lesions far from reach). The REU scoring system (reticular/hyperkeratotic, erosive/erythematous, ulcerative) will be used to evaluate lesions.- Side effects form based on (CTCAE) Common Terminology Criteria for Adverse Version 5 is completed for patients on days 7, 14, 28.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients who receive the mucoadhesive form containing Golnar 3 times a day

Category

Treatment - Drugs

2

Description

Control group: 20 patients who receive triamcinolone mucoadhesive form 3 times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Shokri dental clinic

Full name of responsible person

Elahe Tahmasebi

Street address

Milad dead end, Kharazmi St, Molla Sadra St, Tehran, Tehran Province

City

Tehran

Province

Tehran

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1234567890

Phone

+98 21 8755 9000

Email

Slave.tahmasebi.delfan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Roja Rahimi

Street address

No. 27, North Sarparast St., West Taleghani St.

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8899 8378

Email

rojarahimi@gmail.com

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

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

Tehran University of Medical Sciences

Full name of responsible person

Seyede Zahra Moravej

Position

Ph.D candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyede Zahra Moravej

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All non-personal data of participants without mentioning names; Information about the main messages and all the information obtained from the research is published in the article

When the data will become available and for how long

in the relevant article after its publication

To whom data/document is available

Everyone who has access to the published article

Under which criteria data/document could be used

After publication in the journal

From where data/document is obtainable

to the text of the published article

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

send e-mail to zmoravej@razi.tums.ac.ir

Comments