Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of herbal products (German chamomile or"Matricaria chamomilla" and Common marshmallow or" Althaea officinalis ") based on Persian medicine compared to oral gel triamcinolone in patients with oral lichen planus: A randomizedclinical trial

Protocol summary

Study aim
effectiveness of herbal products of chamomile and marshmallow based on Iranian medicine in the treatment of oral lichen planus

Design
A controlled, randomized,double blind, phase 2 clinical trial with parallel groups on 50 patients, using double blocks for randomization. To blind the drug for both control and control groups, the pharmacist prepares and labels it in identical packaging. These packages are prepared in the same shape, color, and form, and the physician prescribes it to the patient in a blinded manner and based on randomization based on double blocks.

Settings and conduct
In the field of dermatology, at Razi Hospital, patients will be randomly divided into two equal groups. The control group receive 0.1% triamcinolone oral paste) and the intervention group treats with chamomile and marshmallow oral gel topically four times a day. Patients will be treated for two months and then discontinued for one month. After the start of the intervention, patients will follow up monthly at specific periods (0, 1, 2, and 3 months after the intervention). Participants, physicians, and principal investigators will be blinded throughout the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients diagnosed with lichen planus by a dermatologist, with positive pathology, and mild to moderate oral lesions. Exclusion criteria: People with immunodeficiency, diabetes, pregnancy, osteomyelitis and peripheral vascular disease, and use of systemic medications, severe oral lichen planus lesions.

Intervention groups
The intervention group consists of individuals who are randomly selected to receive the drug under study for their oral lichen planus lesion. The control group is also cross-examined by administering a placebo versus the medicine of the intervention group.

Main outcome variables
Age; Gender; Severity of oral lichen planus lesions; Duration of disease

General information

Reason for update

Acronym
HMOLPS

IRCT registration information
IRCT registration number: **IRCT20250911067210N2**
Registration date: **2025-09-30, 1404/07/08**
Registration timing: **prospective**

Last update: **2025-09-30, 1404/07/08**
Update count: **0**

Registration date
2025-09-30, 1404/07/08

Registrant information

Name
Azadeh Zarei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8897 6527

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-17, 1404/07/25
Expected recruitment end date
2026-09-21, 1405/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of herbal products (German chamomile or"Matricaria chamomilla" and Common marshmallow or" Althaea officinalis ") based on Persian medicine compared to oral gel triamcinolone in patients with oral lichen planus: A randomizedclinical trial

Public title
The effect of herbal medicine on oral lichen planus study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of lichen planus by a dermatologist Patients with positive pathology Mild to moderate oral lesions
Exclusion criteria:
People with immunodeficiency Diabetes Pregnancy Osteomyelitis Peripheral vascular disease Use of systemic medications Severe degrees of oral lichen planus lesions
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**
Randomization (investigator's opinion)
Randomized
Randomization description
To minimize heterogeneity between study groups, a block randomization design was implemented to randomly assign participants. Eligible patients will be randomly assigned in a 1:1 ratio to the intervention and control groups. Randomization will be performed using a computer-assisted randomization (RAS) procedure. The sequence will be in alternating blocks of four, with patients stratified. Except for the study pharmacist who will provide the randomization list and the sequential numbering of the drug, the investigators and all patients will be unaware of this list. The allocation sequence is sealed and hidden through sequential numbering.

Blinding (investigator's opinion)
Double blinded
Blinding description
The principles of blinding are that both the drug and the placebo are indistinguishable in size, color, shape, weight, and packaging. The participants in the study, the prescribing physician, and the study investigators are unaware of the allocation of the drug and placebo, and only the pharmacist is aware of the allocation. To hide the drug and placebo and prevent their identification, identically shaped boxes with completely identical conditions that are randomly assigned and coded are used so that this blinding is maintained throughout the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences, Institute of Pharmaceutical Sciences, Teh
Street address
Ahmadieh Health Center, Tabriz Alley, North Sarparast Street, Taleghani Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2025-07-22, 1404/04/31
Ethics committee reference number
IR.TUMS.TIPS.REC.1404.042

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

Change in lesion severity on examination based on REU score

Timepoint

Before the start of the intervention, and then after the intervention at specific time periods (0, 1, 2, and 3 months after the intervention) on a monthly basis

Method of measurement

Clinical exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chamomile and marshmallow oral gel (5% aqueous extract of chamomile flowers and 5% of marshmallow aerial parts (flowers)) four times a day topically for two months

Category

Treatment - Drugs

2

Description

Control group: Oral triamcinolone topical, four times a day for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Azadeh Zarei

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Vahdat e Islami Street

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

Headquarters of Tehran University of Medical Sciences, Qods street, Keshavarz Blvd

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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

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

Azadeh Zarei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Information about patients and the main outcome can be shared.

When the data will become available and for how long
6 months after publication and printing of results

To whom data/document is available
Researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used
For use in other studies or to design new studies

From where data/document is obtainable
Professor Mehrdad Karimi mehrdadkarimi@yahoo.com 00982188976527

What processes are involved for a request to access data/document
The request is registered via email and is responded to after review by members of the research team.

Comments