Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of epigallocatechin gallate (extracted from green tea) loaded nanostructured lipid carriers on the treatment of oral lichen planus

Protocol summary

Study aim
The effect of epigallocatechin gallate (extracted from green tea) loaded nanostructured lipid carriers on the treatment of oral lichen planus

Design
controlled clinical trial, phase 3, with two-parallel groups, duble -blind

Settings and conduct
This study will be conducted in the clinics of the University of Medical Sciences and the dental faculty of Tabriz. The random assignment sequence will be determined by a person not involved in the study using G-Power software. To conceal the allocation of drugs , it will be placed in opaque, sequentially numbered bottles. Qualified people will be placed in two intervention and control groups using the random block method with a block size of 6 and with a 1:1 allocation sequence.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Definite Diagnosis of Lichen Planus via clinial criteria and histopathology, approvement range of 17 to 70 years old; Exclusion Criteria: pregnancy or breastfeeding, usage of Immuno supressor Drugs.

Intervention groups
Intervention group: Mouthwash containing Epigallocatechin gallate loaded nanostructured lipid carriers will be used 3 times a day, 5 cc each time for 4 weeks. Control group: Mouthwash containing Epigallocatechin gallate will be used 3 times a day, 5 cc each time for 4 weeks.

Main outcome variables
Pain intensity, lesion size, Thongprasom scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230823059238N1**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **prospective**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date
2023-09-18, 1402/06/27

Registrant information

Name
Parya Emamverdizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-26, 1402/07/04

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of epigallocatechin gallate (extracted from green tea) loaded nanostructured lipid carriers on the treatment of oral lichen planus

Public title
The effect of epigallocatechin gallate loaded nanostructured lipid carriers on oral lichen planus

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definite Diagnosis of Lichen Planus via Clinial criteria and Histopathology approvement Range of 17 to 70 years old
Exclusion criteria:
Pregnancy or breastfeeding Usage of Immuno supressor Drugs Any treatment that has been done for these injuries
Age
From **17 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be placed in two intervention and control groups using a random block method with a block size of 6 and with a 1:1 allocation sequence. The allocation sequence will be determined by a person not involved in the study using G-Power software, placed in consecutively numbered opaque bottles to conceal drug or placebo allocation, and prepared according to the allocation sequence by The person not involved in the research will be done from number 1 to 46.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines will be prepared by the pharmaceutical company in a completely similar form in terms of shape, color and smell. The participant, researcher, data analyst will be unaware of the type of intervention received.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
3335 5965
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.TBZMED.REC.1402.311

Health conditions studied

1

Description of health condition studied
oral lichen planus
ICD-10 code
L43.8
ICD-10 code description
Other lichen planus

Primary outcomes

1

Description
severity of pain
Timepoint
Before the start of the intervention and 2 and 4 weeks after the intervention
Method of measurement
The severity of pain will be evaluated through visual analogue scale (VAS)

2

Description
The size of lesions
Timepoint
Before the start of the intervention and 2 and 4 weeks after the intervention
Method of measurement
The size of lesions will be measured with paper lace

3

Description
The appearance of lesions
Timepoint
Before the start of the intervention and 2 and 4 weeks after the intervention
Method of measurement
The appearance of lesions will be measured by Thongprasom scale and includes 6 grades: zero = perfectly healthy, 1 = mild white lines without inflammatory regions, 2 = white lines with atrophic

regions smaller than 1 cm2, 3 = white lines with atrophic regions larger than 1 cm2, 4 = white lines accompanied with erosive regions less than 1 cm2, 5 = white lines with erosive areas larger than 1 cm2 .

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mouthwash containing Epigallocatechin gallate loaded nanostructured lipid carriers will be used 3 times a day, 5 cc each time for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Mouthwash containing Epigallocatechin gallate will be used 3 times a day, 5 cc each time for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental faculty at Tabriz university of medical sciences
Full name of responsible person
Parya Emamverdizadeh
Street address
Tabriz University of Medical Sciences, Dental faculty, Golgasht Street, Tabriz.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Parviz Shahabi
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Research department, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahyar Hashemi
Position
Dental Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate Professor

Latest degree
Specialist

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Dentistry

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Person responsible for updating data

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Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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