

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

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

Protocol summary

Registration timing: **prospective**

Study aim

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

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

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Design

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

Registrant information

Name

Parya Emamverdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

emamverdizdeh@tbzmed.ac.ir

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.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Definite Diagnosis of Lichen Planus via clinical criteria and histopathology, improvement range of 17 to 70 years old; Exclusion Criteria: pregnancy or breastfeeding, usage of Immunosuppressant Drugs.

Expected recruitment start date

2023-09-26, 1402/07/04

Expected recruitment end date

2024-05-19, 1403/02/30

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.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Pain intensity, lesion size, Thongprasom scale

Trial completion date

empty

General information

Scientific title

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

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059238N1**

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

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 Clinical criteria and Histopathology improvement Range of 17 to 70 years old

Exclusion criteria:

Pregnancy or breastfeeding Usage of Immuno suppressor 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.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 914 415 3104

Fax

+98 41 3334 6977

Email

emamverdizadeh@bzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

Street address

Research department, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3335 5921

Email

dabirkhanecent@tbzmed.ac.ir

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

Street address

Tabriz University of Medical Sciences, Dental faculty, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

mahyarmh77@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parya Emamverdizadeh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tabriz University of Medical Sciences, Dental faculty,
Golgasht Street, Tabriz.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

emamverdizadeh@bzmed.ac.ir

Person responsible for updating data

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

Street address

Tabriz University of Medical Sciences, Dental faculty,
Golgasht Street, Tabriz.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

mahyarmh77@gmail.com

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