

# 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

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### 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.

#### Trial completion date

empty

#### Main outcome variables

Pain intensity, lesion size, Thongprasom scale

#### Scientific title

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

#### General information

#### 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 cm<sup>2</sup>, 3 = white lines with atrophic regions larger than 1 cm<sup>2</sup>, 4 = white lines accompanied with erosive regions less than 1 cm<sup>2</sup>, 5 = white lines with erosive areas larger than 1 cm<sup>2</sup> .

## 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

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##### 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**

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Golgasht Street, Tabriz.

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**Province**

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## 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**

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**City**

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**Postal code**

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**Phone**

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**Email**

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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