

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of systemic Echinacea on clinical indices of erosive oral lichen planus

Protocol summary

Study aim

Determine and comparison of healing indices of erosive oral lichen planus following the use of systemic Echinacea

Design

Clinical trial with control group, parallel groups, randomized

Settings and conduct

Among the patients referred to Isfahan oral medicine department in 2019-2020 and met the eligibility criteria, 64 patients will be assigned to case and placebo groups using block randomization method. Each patient will take 1 Echinacea tablet 3 times a day with water and special mouthwash. They will take the tablets for 35 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pathologically confirmed patients with erosive oral lichen planus according to WHO criteria, having patient's cooperation and consent, clinical score more than 1 according to modified Thongprasom criteria
Exclusion criteria: pregnancy and lactation, presence of extraoral lesions of lichen planus, presence of other lesions in oral cavity, history of asthma and allergy, patients suffering from systemic conditions such as diabetes, tuberculosis, high blood pressure and life threatening diseases such as cancer

Intervention groups

Each patient in intervention group will receive 105 Echinacea tablets (each 114 mg) (1 tablet every 8 hours for 5 weeks) alongside a mouthwash containing Diphenhydramine, Nystatin, Betamethasone and Aluminium MG. Each patient in placebo group will receive 105 placebo tablets (1 tablet every 8 hours for 5 weeks) alongside a mouthwash containing Diphenhydramine, Nystatin, Betamethasone and Aluminium MG. Each container will have A or B label on them respectively.

Main outcome variables

lesion size change, pain score change, duration of lesion healing, duration of pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046591N1**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

mahsa etemadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3263 2009

Email address

mahsaetmd@res.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-03, 1398/05/12

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of systemic Echinacea on clinical indices of erosive oral lichen planus		and clinician will not know about the content of each container. Data will be given to the statistics advisor in alphabets.	
Public title	Evaluation of the effectiveness of systemic Echinacea on clinical indices of erosive oral lichen planus	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Patients sufering from erosive oral lichen planus refered to isfahan dental school department of oral medicine whose lesions are clinically and pathologically confirmed according to WHO criteria Certaining of the patient's cooperation and consent presence of at least one lichen planus lesion in oral cavity according to modified Thongprasom criteria the clinical score must be more than 1 Exclusion criteria: patients attended another clinical trial in past 3 months pregnancy and lactation presence of lichenoid reactions presence of extraoral lesions use of systemic steroid drugs, analgesics, immunomodulation drugs, NSAIDs a week before trial presence of other lesions in oral cavity history of asthma and allergy patients suffering from systemic conditions such as diabetes, TB, high blood pressure, life threatening diseases and cancer patients suffering from ulcerative colitis, entrogastic diseases, crohns syndrome, behjet`s syndrome, intensive anemia, rheumatoid arthritis, lupus, multiple sclerosis, collagen disorders, leukosis and AIDS history of organ transplantation	Other design features	
Age	From 20 years old to 60 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	2-3	1	
Groups that have been masked	- Participant - Care provider - Data analyser	Ethics committee	
Sample size	Target sample size: 64	Name of ethics committee	Ethics committee of Isfahan University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Hezar jarib St. Isfahan university of medical sciences
Randomization description	Among patients suffering from erosive oral lichen planus referred to Isfahan university of medical sciences, 64 patients who have been examined and met the eligibility criteria will enter the study and a number will be assigned to every patient. Then they will be divided into two groups using block randomization (block size=32) in the random allocation service software. For allocation concealment, sealed coded boxes with same size and weight will be used.	City	Isfahan
Blinding (investigator's opinion)	Double blinded	Province	Isfahan
Blinding description	Placebo and echinacea tablets will be placed in the same containers each with A or B labels on them. The patient	Postal code	8174673461
		Approval date	2019-07-31, 1398/05/09
		Ethics committee reference number	IR.MUI.RESEARCH.REC.1398.234
		Health conditions studied	
		1	
		Description of health condition studied	Erosive oral lichen planus
		ICD-10 code	L43
		ICD-10 code description	Lichen planus
		Primary outcomes	
		1	
		Description	lesion size
		Timepoint	At baseline(before intervention),10,25 and 35 days after using Echinacea tablets
		Method of measurement	graph paper and ruler
		2	
		Description	pain level
		Timepoint	

At baseline(before intervention),10,25 and 35 days after using Echinacea tablets

Method of measurement
Visual Analogue Scale index

Secondary outcomes

1

Description

Duration of lesion healing

Timepoint

At baseline(before intervention),10,25 and 35 days after using Echinacea tablets

Method of measurement

day

2

Description

duration of pain relief

Timepoint

At baseline(before intervention),10,25 and 35 days after using Echinacea tablets

Method of measurement

day

Intervention groups

1

Description

Intervention group: Characteristics of the consumed substance: Echinacea herbal tablets, The chemical composition and its concentration: Each tablet contains 114 mg of dried extract of leachate shoots of Echinacea, The dose: 342 mg daily, Consumption frequency: Three times a day orally, Consumption Duration: 35 days. one spoon of mouthwash: nystatin oral drop 100000 U/G 20-25 drops,4 ampules of betamethasone suspension ,aluminium MG 1 spoon, diphenhydramine syrup 1 spoon

Category

Treatment - Drugs

2

Description

Control group: placebo tablets; Consumption frequency: Three times a day orally, Consumption Duration: 35 days. one spoon of mouthwash: nystatin 100000 U/G 20-25 drops,4 ampule betamethasone suspension ,aluminium MG 1 spoon, diphenhydramine syrup 1 spoon

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental School

Full name of responsible person

Dr.Zahra Saberi

Street address

Oral and Maxillofacial department, School of Dentistry, Isfahan University of Medical Sciences School of Dentistry, St.Hezarjarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

zahra.saberi@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Nakisa Torabinia

Street address

Vice Chancellor for Research of School of Dentistry, Isfahan Unuversity of Medical Sciences School, St.Hezarjarib, Isfahan

City

Isfahan

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Postal code

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Email

Torabinia@dnt.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Saberi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Oral and Maxillofacial department, School of
Dentistry, Isfahan University of Medical Sciences
School of Dentistry, St.Hezarjarib, Isfahan

City

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zahra.saberi@dnt.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Saberi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa Etemadi

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

No. 71D, negin moshtagh complex, bustan St.,
sarvestan St.,jeshir St., moshtagh 2nd St.

City

Isfahan

Province

Isfahan

Postal code

8158166169

Phone

+98 31 3263 2009

Fax**Email**

mahsaemdi@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Not applicable

Title and more details about the data/document

All data can be shared after patients are unrecognizable.

When the data will become available and for how long

6 months After the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use of data under the supervision and agreement of the
Isfahan University of Medical Sciences vice chancellor of
Research and Technology and the project implementer
and to achieve the intended aims in the proposal and
developing review studies

From where data/document is obtainable

Dr Zahra Saberi : zahra.saberi@dnt.mui.ac.ir

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

1-Contact the project implementer via Email and make a
written request for the consent to deliver the data 2-
Seeking contact information of Isfahan University of
Medical Sciences Vice Chancellor of research and
Technology 3-Make a written request to obtain

permission from Isfahan University of Medical Sciences
Vice Chancellor of research and Technology 4-The data
can be accessed only in person from the Department of

Oral Medicine of Isfahan Dental School If there is no
problem data will be accessible in 2 weeks.

Comments