Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 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

Public title
Evaluation of the effectiveness of systemic Echinacea on clinical indices of erosive oral lichen planus
Purpose
Treatment
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, entrogastric diseases, crohns syndrome, behjet`s syndrome, intensive anemia, rheumatoid arthritis, lupus, multiple sclerosis, collagen disorders, leukosis and AIDS history of organ transplantation
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo and echinacea tablets will be placed in the same containers each with A or B labels on them. The patient and clinician will not know about the content of each container. Data will be given to the statistics advisor in alphabets.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jarib St. Isfahan university of medical sciences
City
Isfahan
Province
Isfehan
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: Chracteristics 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

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+98 31 3668 0048

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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

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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

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
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Oral and Maxillofacial department, School of Dentistry, Isfahan University of Medical Sciences School of Dentistry, St.Hezarjarib, Isfahan
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Dentistry student
Latest degree
Medical doctor
Other areas of specialty/work
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No. 71D, negin moshtagh complex, bustan St., sarvestan St.,jeshir St., moshtagh 2nd St.
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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