Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of propolis use on blood level of il-17 in ulcerative oral lichen planus patients

Protocol summary

Summary

Lichen planus (LP), a relatively common mucocutaneous disease, has unknown etiology and potential for malignant transformation. However several researches have been done, but there isn't any standard treatment yet and current methods have many side effects. Among LP related immunologic and inflammatory factors, one issue which recently catches researchers' attention is cytokine "interleukin-17"(IL-17) ,whereas its importance has been shown in several autoimmune diseases. ProPolis, a natural product of honey bees, has been described to have ability of control and reduction of IL-17, and its effectiveness has been investigated in animal studies. In this study, 30 patients with ulcerative oral LP (clinically and histopathologically diagnosed) whome referred to oral medicine department of Tabriz dental faculty were subjected. Serum level of IL-17 will be analyzed in 5cc of blood sample of these patients by ELISA method in a specific kit. During first one month period, patients will be take ProPolis capsules (500mg/daily). Then blood sampling and leveling of IL-17 will be repeated. We will obtain fresh ProPolis from Sabalan Mountains which will be extacted by alcohol solvent at pharmacology faculty of Tabriz. Results will be analyzed by descriptive statistics(standard deviation-mean)and paired sample t-test or its non parametric equivalent(wilcoxon test) by using of spss 16 soft ware.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010111976N1**
Registration date: **2013-02-10, 1391/11/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-10, 1391/11/22

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-04, 1391/11/16

Expected recruitment end date

2013-02-14, 1391/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of propolis use on blood level of il-17 in ulcerative oral lichen planus patients

Public title

Effect of propolis use on blood level of il-17 in ulcerative oral lichen planus patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with ulcerative oral lichen

planus with clinical manifestations and histopathological criteria including: 1-Areas of hyper parkeratosis or hyper orthokeratosis, often with thickening of granular cell layer and saw-toothd appearance to the retepegs. 2-liquefaction degeneration or necrosis of basal cell layer. 3-sub epithelial band like infiltration of T lymphocyte and macrophage. Exclusion criteria: any factor that cause lichenoid reaction like as drug use or presence of amalgam restoration adjucent to lesions; any disease that suppresses immune system,such as HIV or Iv drug abuse,and any disease in which doing biopsy has medical complications; use of drug during one month ago for treatment of olp or use of antibiotic or corticosteroid or any drug that can suppress lymphocyte activity(for confidence that drugs don't change serum level of il-17); report of dysplasia or malignancy in patients pathology; history of dermal or digestive hypersensitivity to propolis; unwillingness to participate in study at any stages and report of side effects from patients or researchers.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy of tabriz university of medical sciences

Street address
Tabriz-Golgasht street-university of medical sciences - central building no 2-3th floor.

City
Tabriz

Postal code
5166614713

Approval date
2013-01-07, 1391/10/18

Ethics committee reference number
91168

Health conditions studied

1

Description of health condition studied
oral lichen planus

ICD-10 code
L-43

ICD-10 code description
lichen planus

Primary outcomes

1

Description
serum level of il-17

Timepoint
At the begining of research-one month later

Method of measurement
Elisa kit (ebio science company)

Secondary outcomes

1

Description
size of lesions

Timepoint
At the beigining of the research-one month later

Method of measurement
Mesurment of lesion size at the begining of research with digital colis and then mark the changes by researcher in future follwing.

2

Description
Pain and burning sensation

Timepoint
At the beigining of the research-one month later

Method of measurement
VAS scale

Intervention groups

1

Description
propolis capsule 500 mg daily for one month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral Medicine Department- Dental Faculty-Tabriz University of Medical Sciences
Full name of responsible person
Dr Ali Taghavi Zenuz
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Tabriz- Golgasht sreet- Dental School- Oral Medicine Department
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Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Tabriz University of Medical Sciences
Full name of responsible person
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Tabriz- Golgasht street- Tabriz University of Medical Sciences- Central building no 2- 3th floor
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty