

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The assessment of the therapeutic effect of bee propolis on oral Lichen Planus treatment.

Protocol summary

Study aim

The determination of therapeutic effect of bee propolis on the oral Lichen Planus treatment.

Design

Clinical trial with control group, with parallel group, double-blind, randomized, phase 3 on 40 patients. The random numbers table was used to randomize.

Settings and conduct

Patients who referred to the dental academic clinic or private centers in Bojnourd with OLP diagnosed by oral specialists, submit their initial information first and then in order to randomize the process, person "A" uses a computer and a table of random numbers to create a random sequence and people are divided into two "A" and "B" groups. Then, in the next step, person "B" prescribes medicine for one group and placebo for the other group. Group "A" consumes Propolis in the form of mouthwash with the dose of 500 mg according to the manufacturer's instructions and group "B", a placebo with the same form as the main drug is prescribed. The operator (the person prescribing the medicine) and the patient are not aware of any medicine or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are diagnosed with OLP by an oral specialist. People who have been willing to participate in the study and sign the informed consent form. Exclusion criteria: Patients with any past or present immunological disease or disorder. Patients with any past or present allergic disease or disorder. Pregnant and lactating women.

Intervention groups

The Intervention Group consumes propolis in the form of mouthwash with the dose of 500 mg according to the manufacturer's instructions. The Control Group is given a placebo with a very similar form to the main drug and in the same way.

Main outcome variables

Extent of Atrophic areas; Extent of Ulcerative areas; Extent of Keratotic areas; Intensity of pain and irritation;

Type of intervention; Patient's Gender; Patient's age.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210112050013N2**

Registration date: **2021-06-30, 1400/04/09**

Registration timing: **prospective**

Last update: **2021-06-30, 1400/04/09**

Update count: **0**

Registration date

2021-06-30, 1400/04/09

Registrant information

Name

Javid Rasekhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3251 3000

Email address

j.rasekhi@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the therapeutic effect of bee propolis on oral Lichen Planus treatment.

Public title

The assessment of the therapeutic effect of bee propolis on oral Lichen Planus treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are diagnosed with OLP by an oral specialist. People who have been willing to participate in the study and sign the informed consent form.

Exclusion criteria:

Patients with any past or present immunological disease or disorder. Patients with any past or present allergic disease or disorder. Pregnant and lactating women. Susceptible Patients to bee sting and products. Patients who have used systemic or topical Glucocorticosteroids at least over the past one month. Patients with Lichen Planus extra-oral manifestations. Patients with any continuous medication history. Patients with oral Lichen Planus with evidence of dysplastic changes in the oral mucosa or a history of such changes in the past.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: Uninformed about being in the Intervention or Control Group. Researcher: Uninformed about the patients in Intervention or Control Group and prescribing drugs or placebo. Outcome Evaluator: Uninformed about the patients in the Intervention or Control Group and prescribing drugs or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Sciences

Street address

No. 12, Ferdowsi 19, South Ferdowsi St.

City

bojnourd

Province

North Khorasan

Postal code

9418654360

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.NKUMS.REC.1399.144

Health conditions studied

1

Description of health condition studied

Lichen planus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Extent of Atrophic areas: The area of Atrophic areas measured by caliper in square millimeters. Extent of Ulcerative areas: The area of the wound area measured by the caliper. Area of Keratotic areas: Area of Keratotic areas measured by caliper. Intensity of pain and irritation: The scale of pain and oral mucosa irritation that the patient reports according to VAS.

Timepoint

At the beginning of study and a month after the start of the study

Method of measurement

To measure the area of the affected areas, the largest lesion diameters are measured by a caliper and their product is considered as the area of the target area. If the patient has similar lesions in several areas, the area of all these areas will be added together and this amount will be reported. The scale of pain and irritation is measured by the Visual Analogue Scale. This method of measurement asks the patient to rate their pain and irritation from 0 (with no pain and irritation) to 10 (the most severe pain and irritation).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A consumes Propolis in the form of mouthwash with a dose of 500 mg, according to the manufacturer's instructions once or twice a day after brushing; First rinse the mouth with water or serum (normal saline) and then immediately use mouthwash with a plastic cup on the glass. Each mouthwash should last at least 2-3 minutes. Avoid eating and drinking for 30 minutes after using the mouthwash.

Category

Treatment - Drugs

2

Description

Control group: Group B consumes placebo which is prescribed in the same form as the main drug and in the same way. Use mouthwash once or twice a day after brushing; First rinse the mouth with water or serum (normal saline) and then immediately use mouthwash with a plastic cup on the glass. Each mouthwash should last at least 2-3 minutes. Avoid eating and drinking for 30 minutes after using the mouthwash.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bojnourd Dental School Clinic

Full name of responsible person

Dr. Javid Rasekhi

Street address

No. 12, Ferdowsi 19, South Ferdowsi St.

City

Bojnourd

Province

North Khorasan

Postal code

9418654360

Phone

+98 58 3272 9338

Email

forooghsajedii12@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Javid Rasekhi

Street address

No. 12, Ferdowsi 19, South Ferdowsi St.

City

bojnourd

Province

North Khorasan

Postal code

9418654360

Phone

+98 58 3272 9338

Email

forooghsajedii12@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Javid Rasekhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 12, Ferdowsi 19, South Ferdowsi St.

City

Bojnourd

Province

North Khorasan

Postal code

9418654360

Phone

+98 58 3272 9338

Email

forooghsajedii12@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Javid Rasekhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 12, Ferdowsi 19, South Ferdowsi St.

City

bojnourd

Province

North Khorasan

Postal code

9418654360

Phone

+98 58 3272 9338

Email

forooghsajedii12@gmail.com

No. 12, Ferdowsi 19, South Ferdowsi St.

City

bojnourd

Province

North Khorasan

Postal code

9418654360

Phone

+98 58 3272 9338

Email

forooghsajedii12@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

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

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Javid Rasekhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address