Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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
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