

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of topical cream containing processes of *Chelidonium majus* and *hyoscyamus niger* with propolis on psoriasis

Protocol summary

Study aim

Determination effect of a topical cream containing *Chelidonium Majus* and *Hyoscyamus Niger* with Propolis on Psoriasis

Design

The randomized clinical trial with an intervention and a control group, double-blind, phase 3 on 88 patients

Settings and conduct

A double-blind study is performed on 88 psoriasis patients in Shahid Beheshti of Kashan hospitals. The doctor and the patient do not know the type of treatment. The patients receive topical cream containing *Chelidonium majus* and *Hyoscyamus niger* with Propolis for 6 weeks. The duration of each cream will be 6 days and the treatment will be done three times a day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: known case of psoriasis; Clinical judgment of the specialist physician based on receiving the product; Patients with psoriasis during 3 months, the age range of 18 to 85 years. Exclusion criteria : Existence of any history of allergy to any herbal product; pregnancy for females.

Intervention groups

The intervention group is included 44 psoriasis patients . During three weeks, topical cream containing 0.5 grams of *Chelidonium majus* and 0.5 grams of *Hyoscyamus niger* with 2 grams of Propolis is used. The duration of each cream will be 6 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period.

Main outcome variables

Quantitative and qualitative evaluation of wounds extent and redness of the skin and the extent of involvement of different parts of the body and itching; expression of TNF- α , IL-17 gene.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047462N4**

Registration date: **2022-01-15, 1400/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-15, 1400/10/25**

Update count: **0**

Registration date

2022-01-15, 1400/10/25

Registrant information

Name

morteza kosari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5434 6622

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yeganehbadi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical cream containing processes of *Chelidonium majus* and *hyoscyamus niger* with propolis on psoriasis

Public title

Effect of Chelidonium majus and hyoscyamus niger with propolis on psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

known case of psoriasis Clinical judgment of the specialist physician based on receiving the product Patients with psoriasis during 3 months, and are in the age range of 18 to 85 years

Exclusion criteria:

Existence of any history of allergy to any herbal product pregnancy for females

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples with the help of Sealed Envelope Ltd. 2017 is divided into two groups of intervention and control in the form of blocks of 4 and 6 (selection of these blocks randomly). Each of these blocks has an equal number of control and intervention groups. A special number is assigned to each prescription drug [intervention and control (placebo)]. The doctor and the patient are not aware of the medication or placebo, and only the epidemiologist, as one of the executors, knows the number or code on registered on creams.

Blinding (investigator's opinion)

Double blinded

Blinding description

A cream that has an active ingredient with a cream that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the solution themselves do not differ in terms of color, and are completely indistinguishable. The important point is that the patient is told that the topical cream used for the patient may be medication or medication. Clinicians and patients will be blinded

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Shahid Beheshti Hospital, University of Medical Sciences, Kashan, Iran.

City

Kashan

Province

Isfahan

Postal code

87159/81151

Approval date

2021-04-28, 1400/02/08

Ethics committee reference number

IR.KAUMS.REC.1400.002

Health conditions studied**1****Description of health condition studied**

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes**1****Description**

PASI Score

Timepoint

At the beginning of the study, 4, 7, 14, 28 and 40 days after treatment

Method of measurement

Evaluated quantitatively and qualitatively of wounds extent and redness of the skin and the extent of involvement of different parts of the body and itching .

2**Description**

Expression of TNF- α , IL-17 gene

Timepoint

After 40 days

Method of measurement

Real Time PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group is included 44 patients with psoriasis. During three weeks, topical cream containing 0.5 grams of Chelidonium majus and 0.5 grams of Hyoscyamus niger with 2 grams of Propolis is used. The duration of each cream will be 6 days and the treatment will be done tree a day. The patient receives a maximum of 3 creams during the treatment period.

Category

Treatment - Drugs

2

Description

Control group: Topical cream with no active ingredients is used for three weeks. The duration of use of each cream will be 6 days. The patient receives a maximum of 3 creams during the treatment period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Morteza Kosari

Street address

Ghotb Ravandi Blvd, Shahid Beheshti hospital of Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Banafsheh

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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

Kashan University of Medical Sciences

Proportion provided by this source

20

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

Kashan University of Medical Sciences

Full name of responsible person

Morteza Kosari

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiology

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Latest degree

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about participants such as age, gender, level of education and employment will be reported. The treatment protocol and the duration of treatment process will be reported. Therapeutic results of the product and possible side effects will be reported.

When the data will become available and for how long

The start of the access period will be 6 months after patent presentation or 1 months after article publication.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutes.

Under which criteria data/document could be used

The data printed in the article is accessible.

From where data/document is obtainable

Moderator: Morteza Kosari Email address:
kosarimorteza12@gmail.com

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

This access will be based on the treatment protocol in patients and treatment results, and includes effective ingredients and how to make the privacy cream of the project implementers. We will try to respond to researchers as soon as possible.

Comments