Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
he 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)

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+98 31 5434 6622

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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
Isfehan
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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Ghotbe Ravandi Blvd, Kashan University of Medical Sciences

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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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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