Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the efficacy and safety of Purslane (Portulaca oleracea) Product on Clinical Symptoms of Mild to Moderate Chronic Hand Dermatitis

Protocol summary

Study aim

Determination of efficacy and safety of Portulaca oleracea product on clinical signs of mild to moderate chronic dermatitis

Design

Clinical trial with control group, parallel, double blinded, randomized, sample size: 70 patients

Settings and conduct

In this double-blind study, patients with mild to moderate chronic dermatitis referred to traditional medicine clinics are approved by a dermatologist and randomly divided into intervention and control groups. Before studying, the consent form and related questionnaires are completed and the dermatitis site is photographed. The drug is delivered to the patient. At the end of the second, fourth and eighth weeks, after the intervention, the patient is followed up and the relevant forms are completed, and the dermatitis is photographed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic unilateral or bilateral hand dermatitis, including occupational, allergic or irritative dermatitis, age range 18 to 70 years, referred to traditional health center, willingness and satisfaction to participate in the study. exclusion criteria: patients under 18 years, patients over 70 years, lactation, pregnancy, severe dermatitis, patients with underlying diseases such as cardiovascular failure, diabetes, immunodeficiency, autoimmune diseases, spinal cord diseases, patients taking drugs for diseases Other, other acute illness during treatment, infection at the site of dermatitis, patients sensitive to Portulaca.

Intervention groups

The control group received placebo syrup and Vaseline cream and the intervention group received Portulaca oleracea syrup and Vaseline cream.

Main outcome variables

Erythema, edema, fissure, scaling, itching, dryness, skin thickness, drug side effects, quality of life index in skin diseases, recurrence of symptoms after treatment, overall satisfaction of patients with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048040N1**
Registration date: **2020-08-08, 1399/05/18**
Registration timing: **prospective**

Last update: **2020-08-08, 1399/05/18**
Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Sedigheh Rastegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

rastegar.sedigheh54@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of Purslane (Portulaca oleracea) Product on Clinical Symptoms of Mild to Moderate Chronic Hand Dermatitis

Public title
The effect of Portulaca oleracea syrup on mild to moderate chronic hand dermatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic unilateral or bilateral hand dermatitis, including occupational dermatitis, allergic dermatitis or irritative dermatitis Age range 18 to 70 years Willingness and satisfaction to participate in the study Referred to traditional medicine center
Exclusion criteria:
Breastfeeding Pregnancy Patients with severe dermatitis Patients with underlying diseases such as cardiovascular failure, diabetes, immune deficiency, autoimmune diseases, spinal cord diseases Patients taking medication for their other illnesses Patients who develop another acute illness during treatment Patients who have an infection at the site of their dermatitis Patients who are allergic to Portulaca oleracea
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization: Randomization unit block: Individual Randomization tool: Random number table How to make a sequence: In a random number table, a number is randomly selected from the table and arranged in rows or columns in the up and down and left or right numbers. Next are selected. Because the number of modes of 4 blocks for two groups is 6 modes, numbers higher than 6 and zero are ignored in the table and each digit specifies the desired block.
Blinding (investigator's opinion)
Double blinded
Blinding description
Portulaca oleracea and placebo have been coded for blinding. The patient, researcher, and analyzer are also unaware of the type of drug administered.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak, Yaman Ave., Sh. Aarabi Ave., Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.278

Health conditions studied

1

Description of health condition studied
mild to moderate chronic dermatitis
ICD-10 code
L30.9
ICD-10 code description
Dermatitis, unspecified

Primary outcomes

1

Description
Erythema
Timepoint
Week zero, the end of the fourth and eighth weeks
Method of measurement
HECSI Scale

2

Description
edema
Timepoint
Week zero, the end of the fourth and eighth weeks

Method of measurement
HECSI Scale

3

Description
fissure
Timepoint
Week zero, the end of the fourth and eighth weeks
Method of measurement
HECSI Scale

4

Description
scaling
Timepoint
Week zero, the end of the fourth and eighth weeks
Method of measurement
HECSI Scale

5

Description
itching
Timepoint
Week zero, the end of the second, fourth and eighth weeks
Method of measurement
VAS Scale

6

Description
dryness
Timepoint
Week zero, the end of the second, fourth and eighth weeks
Method of measurement
VAS Scale

7

Description
skin thickness
Timepoint
Week zero, the end of the second, fourth and eighth weeks
Method of measurement
VAS Scale

8

Description
drug side effects
Timepoint
Week zero, the end of the second, fourth and eighth weeks
Method of measurement
Question from the patient

Secondary outcomes

1

Description
Dermatology life quality index
Timepoint
Week zero, the end of the fourth and eighth weeks
Method of measurement
DLQI questionnair

2

Description
Patients' overall satisfaction with treatment
Timepoint
End of the fourth week
Method of measurement
Likert Scale

3

Description
Recurrence of symptoms after treatment
Timepoint
the end of the eighth week
Method of measurement
Question from the patient

Intervention groups

1

Description
Intervention group: Intervention group: Recipient of Portulaca oleracea syrup (25 mg/ ml) 10 cc three times a day for 4 weeks orally prepared to contain aqueous extract of Portulaca oleracea and prepared by the traditional pharmacy group of Shahid Beheshti School of Traditional Medicine, Samin Vaseline cream produced by Golafshan company should be rubbed on the dermatitis area every night as a surface layer for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Control group: 10 cc placebo syrup recipient three times a day for 4 weeks orally and prepared by the traditional pharmacy group of Shahid Beheshti School of Traditional Medicine. Rub a surface layer for 4 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Dr. Shariat Panahi Traditional Medicine Health Center

Full name of responsible person
Sedigheh Rastegar

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No8, Shams Alley, In front of Tavanir Ave., Vali-Asr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi

Street address
5th Floor, Bldg No.2 SBUMS, Sh. Aarabi Ave, Yaman Ave, Velenjak

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sedigheh Rastegar

Position
MD, MPH, PhD Candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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No8, Shams Alley, In front of Tavanir Ave., Vali-Asr Ave., Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Sedigheh Rastegar

Position
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sedigheh Rastegar

Position

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Latest degree

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publication of the results in the form of a doctoral dissertation and an ISI article

When the data will become available and for how long

After PhD thesis defence

To whom data/document is available

public

Under which criteria data/document could be used

for research reasons

From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

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

Approval of the relevant responsible

Comments