

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison between the efficacy of topical product of Sambucus ebulus and Hydrocortisone on the clinical severity of patients with hand eczema

Protocol summary

Study aim

Efficacy of topical products of sambucus ebulus in clinical severity of patients with hand eczema

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

This research, will be done on patients,aged18to60 years old, with hand eczema. This study will be done at Yahya Nejad hospital inBabol, andBaran(skin specialized clinic)in Arak.The patients are randomly assigned to either of the following groups:1. group that recieves the topical product of sambucus ebulus 2. group that recieves one percent Hydrocortisone cream. The patients will be treated for six weeks. Patients are visited4 time points:1. at first attending session 2. at 14th day 3. at 28 th day 4. at 42th day. In each visit, theDermatology Life Quality Index(DLQI) questionnaire and the Hand Eczema Severity Index will be completed for them. Each time photos will be captured of skin damages. After the forth weeks, we will give them 20 jujubes.every day for two weeks.They should boil them in the 4 glasses of water and after boiling , 3 glasses of water will be remained.They will drink every 8 hours , one glass of this water and also in this two weeks they should continue use of the topical drug prescribed in this study on their group.

Participants/Inclusion and exclusion criteria

Entry requirements: 1, aged 18 to 60 years; Conditions of non-arrival: 1, pregnant mothers

Intervention groups

The topical product from the leaf ofsambucus ebulus has been developed as an intervention group and one percent Hydrocortisone cream as a control group.

Main outcome variables

The clinical severity of hand eczema;DLQI;Rate of healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170930036486N2**

Registration date: **2018-05-17, 1397/02/27**

Registration timing: **prospective**

Last update: **2018-05-17, 1397/02/27**

Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 4730

Email address

a.moradi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of topical product of

Sambucus ebulus and Hydrocortisone on the clinical severity of patients with hand eczema

Public title

Investigating the effect of Sambucus ebulus on hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 60 years Patients with hands eczema who have not received any topical medication from the 14 days prior to study

Exclusion criteria:

Pregnant mothers Nursing mothers The presence of underlying diseases of the kidney, liver, heart, diabetes, History of drug allergy Patients with obsessive-compulsive disorder or other mental illness that interferes with the study Use of Systemic Corticosteroids or Immunosuppressives over the past 4 weeks Localized infection in the place of eczema

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: At first, blocks containing 4 of two treatments (Sambucus ebulus or Hydrocortisone) are written with different possible combinations, each given a number, and then using the random number table, each of the 4 blocks, one Of these compounds is devoted.

Blinding (investigator's opinion)

Double blinded

Blinding description

The form of the drug in the same tubes is provided by the pharmacologist. The smell of drugs is largely similar. The researcher does not know the content of the tubes and only the biostatistician knows about it. Patients are also unaware of the contents of the tubes. The conscientious consent will be given to patients and will be explained to them that there are two groups in this study : case and control and they will be in one of these groups by randomization.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University of Medical Sciences

Street address

Gang Afrooz street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2017-11-18, 1396/08/27

Ethics committee reference number

MUBABOL.HRI.REC.1396.112

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

Hand eczema

ICD-10 code

L20-L30

ICD-10 code description

Dermatitis and eczema

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

severity of hand eczema

Timepoint

Before the intervention begins, 14, 28, 42th day after starting of treatment

Method of measurement

Hand eczema severity index

2**Description**

Dermatology Life Quality Index

Timepoint

Before the intervention begins, 14, 28, 42th day after starting of treatment

Method of measurement

Dermatology Life Quality Index questionnaire

Secondary outcomes

1

Description

Rate of healing

Timepoint

Before the intervention begins, 14, 28, 42th day after starting of treatment

Method of measurement

Hand eczema severity index

Intervention groups

1

Description

Intervention group:Topical product of sambucus ebulus.one gram.twice a day,six weeks.After the forth weeks, we will give them 20 jujubes.every day for two weeks.They should boil them in the 4 glasses of water and after boiling , 3 glasses of water will be remained.They will drink every 8 hours , one glass of this water.

Category

Treatment - Drugs

2

Description

Control group:Hydrocortisone cream.one gram.twice a day,six weeks.After the forth weeks, we will give them 20 jujubes.every day for two weeks.They should boil them in the 4 glasses of water and after boiling , 3 glasses of water will be remained.They will drink every 8 hours , one glass of this water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nejad hospital and Baran clinic

Full name of responsible person

Akram moradi farahani

Street address

Farhang intersection in Babol andShahid shiroodi street in Arak

City

Babol and Arak

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4730

Fax

+98 11 3219 4728

Email

a.moradi@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Gang Afrooz street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4730

Email

seyyedali1357@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Akram moradi farahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Gang Afrooz street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4730

Fax

+98 11 3219 4728

Email

a.moradi@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Gang Afrooz street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4730

Email

seyyedali1357@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Akram Moradi Farahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Gang Afrooz street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4730

Fax

+98 11 3219 4728

Email

a.moradi@mubabol.ac.ir

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

To publish the article, it will be available to the journal

When the data will become available and for how long

available after publishing the manuscript

To whom data/document is available

depend on the results, it will be decided

Under which criteria data/document could be used

depend on the results, it will be decided

From where data/document is obtainable

seyyedali1357@gmail.com

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

After the permission of the Babil University of Medical Sciences, there is the possibility of transferring the documentation

Comments