Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Immunosupressives 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 ofBabol 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

Assisstant 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