

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Sambucus ebulus 5% solution in the treatment of Paederus Dermatitis

Protocol summary

Summary

Paederus dermatitis, also known as dermatitis linearis is a peculiar irritant contact dermatitis characterized by erythematous and bullous lesions of sudden onset on exposed areas of the body. Iranian traditional medicine uses the S. ebulus in treating some inflammatory cases such as, bee and nettle bites, arthritis and sore-throat. In addition, it has been reported to be anti-bacterial, antioxidant, convenient in treatment of burns and infectious wounds, edema, eczema, urticaria, inflammation and rheumatism. These effects gave us a solid basis to make use of S. ebulus in treatment of paederus dermatitis. This study was designed to evaluate the clinical efficacy of S. ebulus 5% solution in patients affected by paederus dermatitis. Fruit were dried at room temperature and coarsely ground before extraction. Weighed amount of powdered sample was fractionated by successive solvent extraction at room temperature by percolation with hexane then ethyl acetate and finally methanol successively. To evaluate the clinical effect of ethanolic 5% solution, 60 patients will include blind and randomly in two groups, that administer S. ebulus ethanolic 5% solution or ethanol 70. All of patients will use a local hydrocortisone ointment too. The effects of drugs in terms of affecting on itching, burning, pain, inflammation, healing rate, drying the wound and infections will study. Four levels, namely, ineffective (value zero), average effect (value one), good effect (value two) and great effect (value three) chose for evaluation. All patients were visited or asked every 12 hr. The preparations will use locally 3 times a day. Only patient with the beginning of lesion less than 24 hours will enter to study. Any adverse drug reaction will considered, too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302132342N3**

Registration date: **2013-03-09, 1391/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

Mohammad Reza Rafati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3083

Email address

mrrafati@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-01-02, 1389/10/12

Expected recruitment end date

2011-10-01, 1390/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Sambucus ebulus 5% solution in the treatment of Paederus Dermatitis

Public title

The effect of Sambucus ebulus in the treatment of Paederus Dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age: 10-60 years; Diagnosis of Paederus dermatitis; Lasting at least 24 hours from the beginning wound signs. Exclusion criteria: Age out of mentioned range; Pregnancy; Diseases or drug using associated with impaired immune system or absence of natural skin repair

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mazandaran University of Medical Sciences, Vice-chancellor for research, Dr. Mohammad Reza Haghshena

Street address

Moallem square

City

Sari

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

54-1389

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

Paederus dermatitis

ICD-10 code

L24.9

ICD-10 code description

Irritant contact eczema NOS

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

Pain

Timepoint

At the beginning of study and then every 12 hours

Method of measurement

questionare

2**Description**

Burning

Timepoint

At the beginning of study and then every 12 hours

Method of measurement

questionare

3**Description**

Lesion size

Timepoint

At the beginning of study and then every 24 hours

Method of measurement

Centimeter square

Secondary outcomes**1****Description**

Treatment duration

Timepoint

The end of treatment

Method of measurement

Hour

2**Description**

Incidence of infection

Timepoint

Each 24 hours

Method of measurement

Physician examination

Intervention groups

1

Description

Intervention group will receive S. ebulus fruit extract 5% solution and hydrocortisone ointment for locally 3 times a day.

Category

Treatment - Drugs

2

Description

Patients in control group will receive ethanol 70° and hydrocortisone ointment for locally 3 times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Booalisina hospital

Full name of responsible person

Dr Masoud Golpur

Street address

Skin office, Pasdaran street

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences, Vice-chancellor for research

Full name of responsible person

Dr Haghshenas

Street address

Moallem square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences, Vice-chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

College of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Mohahammadali Ebrahimzadeh

Position

Ph.D

Other areas of specialty/work

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Person responsible for updating data

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty