

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

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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**

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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Dr Mohammadreza Rafati

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Ph.D

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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*