

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy and safety of topical naloxone in control of chronic pruritus in patients with neurodermatitis

Protocol summary

Summary

Purpose: to evaluate the efficacy and safety of topical Naloxone® to control chronic pruritus in patients with neurodermatitis. Design: This is a Phase I Randomized Controlled Clinical Trial Double Blind study on the patients with neurodermatitis. Patients will randomly be assigned to two groups with 35 patients. Setting and conduct: Patients will be treated with an antihistamine (e.g. Citrizine® 10ml daily), as prescribed by a dermatologist. Patients in the treatment and control group will receive topical formulation of Naloxone® and placebo on the affected areas based on the FINGER TIP UNIT role, twice a day (morning and evening) for a period of 4 weeks. Participant: Patients who have been diagnosed with neurodermatitis by a physician. Intervention: Patients in the treatment group will receive topical formulation of Naloxone® on the affected areas, twice a day (morning and evening) for a period of 4 weeks. Main outcome measure: Pruritus score and Quality Life Quality Index

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702231165N18**

Registration date: **2017-05-28, 1396/03/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-28, 1396/03/07

Registrant information

Name

Yunes Panahi

Name of organization / entity

Scientific title

Evaluation of efficacy and safety of topical naloxone in control of chronic pruritus in patients with neurodermatitis

Public title

Evaluation of efficacy of topical Naloxone® in control of neurotic pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patient has no addiction; have not been treated with any form of topical steroids; diagnosis of neurodermatitis has been confirmed by a physician; the content form should have been completed by the patient; age between 25 and 65 years; have no other skin disorders; accessible at all times during the trial; do not leave the treatment after one week; do not have

allergy to the medication. Exclusion criteria: when disease become uncontrollable; severe reaction or allergy to the medication; patients' age less the 25 and more than 65 years

Age

From **70 years** old to **30 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Islamic Azad University of Pharmaceutical Science

Street address

Islamic Azad University of Pharmaceutical Science; Yasaman alley; Yakhchal street; Doctor shariatie; Tehran; Iran

City

TEHRAN

Postal code

19395-6466

Approval date

2016-03-16, 1394/12/26

Ethics committee reference number

IR.IAU.PS.REC.1394.44

Health conditions studied

1

Description of health condition studied

Neurodermatitis

ICD-10 code

L98.1

ICD-10 code description

Neurotic excoriation

Primary outcomes

1

Description

Severity of itching area

Timepoint

Before intervention; after intervention

Method of measurement

Standard Questionaries

2

Description

Distribution of itching area

Timepoint

Before intervention; after intervention

Method of measurement

Standard Questionaries

3

Description

Quality of life

Timepoint

Before intervention; after intervention

Method of measurement

Standard questionaries

Secondary outcomes

1

Description

Itching Frequency

Timepoint

Before intervention; After intervention

Method of measurement

Standard Questionaries

Intervention groups

1

Description

Control group: Patients in the control group will receive topical placebo formulation, twice daily (morning and evening) for a period of four weeks.

Category

Placebo

2

Description

Intervention group: The Patients in the treatment group will receive topical formulation of Naloxone® on the affected areas, twice a day (morning and evening) for a period of four weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr. Yunes Panahi

Street address

Nosrati Ave., South sheykhbahae St., Mollasadra St.

City

Tehran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of medical sciences

Full name of responsible person

Dr. Yunes Panahi

Street address

Baqiyatallah University of medical sciences,
Sheykhbahae St., Mollasadra St.,

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Baqiyatallah University of medical sciences

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**

Baqiatallah University of Medical Science

Full name of responsible person

Dr. Yunes Panahi

Position

Professor/ PharmD

Other areas of specialty/work

Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Web page address

Person responsible for updating data

Contact

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