Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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 neurodermitis. Design: This is a Phase I Randomized Controlled Clinical Trial Double Blind study on the patients with neurodermitis. 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 neurodermitis by a physicain. 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

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

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

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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

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 neurodermitis 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 Freqency

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 sheykhbahaee St., Mollasadra St.
City
Tehran

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, Sheykhbahaee 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
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Baqiatallah University of Medical Science, Sheykh Bahaei St.,Mollasadra St.,
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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