Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the Efficacy and Safety of Topical Naloxane Ointment on Controlling of Chronic Prupritus Induced By Chemical Injuries

Protocol summary

Summary

The main goal of this study will be evaluation the efficacy and safty of topical naloxone in control of chronic pruritus Induced By Chemical Injuries. Patients who have been diagnosed by physition randomly divided in two groups with a sample size of 35 persons. This study is a double blind RCT(randomise clinical trial). The study population are patients with a clinical diagnosis of chronic pruritus induced by chemical injuries. They will be a candidate for this study. Inclusion criteria: 1. not addicted to opioids; 2. not treated with topical steroids; 3. diagnosis of chronic pruritus induced by chemical injuries confirmed by physition. The patients will enter randomly in two groups of 35 patients. Patients in both group (intervention and control) shuold be receive topical formulation of naloxone in the morning and evening for 4 weeks. (finger tip unit) on the affected areas. Our expected consequences is reducing the severity and extent of itching area. All the above will be evaluation base on standard questionaires such as pruritus score and DLQI .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702221165N17**
Registration date: **2017-03-29, 1396/01/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-29, 1396/01/09

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Personal

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 the Efficacy and Safety of Topical Naloxane Ointment on Controlling of Chronic Prupritus Induced By Chemical Injuries

Public title

Evaluation the efficacy of topical naloxane on Controlling of Chronic Prupritus Induced By Chemical Injuries

Purpose

Treatment

Inclusion/Exclusion criteria

1. self-satisfiction form should be filled by the patient; 2. the patients shouled be between 25-65 years old; 3. the Rx of pruritus induced by chemical gas shouled be diagnosed; 4. the patients shouldn’t have any other skin disorders; 5. the patients don’t use any topical steroids; 6. the patients shouldn’t be addict; 7. the patients be

accessible; 8. the patients don't leave the treatment more than one week; 9. the patients don't have allergy to drug; 10. if the disease become uncontrolabe.

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

2-3

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

The persons who are studied should not be addict.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Azad University of Pharmaciutical Sciences

Street address

Azad University of Pharmaciutical Sciences. Yakhcal St. Dr Shariati street

City

Tehran

Postal code

19395-6466

Approval date

2016-03-16, 1394/12/26

Ethics committee reference number

IR.IAU.PS.REC.1394.45

Health conditions studied

1

Description of health condition studied

Chronic Prupritus Induced By Chemical Injuries

ICD-10 code

L24; L29

ICD-10 code description

Irritant contact dermatitis; Pruritus

Primary outcomes

1

Description

pruritus sevsrity

Timepoint

at the bigging off intervention,at the end of intervention

Method of measurement

standard questionaries

2

Description

pruritus distribion

Timepoint

at the bigging off intervention,at the end of intervention

Method of measurement

standard questionaries

Secondary outcomes

1

Description

pruritus frequency

Timepoint

at the bigging off intervention,at the end of intervention

Method of measurement

standard questionaries

2

Description

pruritus period

Timepoint

at the bigging off intervention,at the end of intervention

Method of measurement

standard questionaries

3

Description

quality of sleeping

Timepoint

at the bigging off intervention,at the end of intervention

Method of measurement

standard questionaries

Intervention groups

1

Description

Topical naloxan 2% formulationintervention group: 35 person will recive topical naloxan formulation, two times a day (in the morning and evening) for 4 weeks. At the begining of the study, standard questionaris will fill by the pationt and at the end of the study again to evaluate the effects of drug.

Category

Treatment - Drugs

2

Description
Control group: 35 person will recive topical palacebo formulation, two times a day (in the morning and evening) for 4 weeks. at the begining of the study,standard questionaris will fill by the pationt and at the end of the study again to evaluate the effects of drug.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Baghiyatallah Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baghiyatallah University
Full name of responsible person
Dr. Yunes Panahi
Street address
Baghiyatallah University, Molla sadra street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Baghiyatallah University
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
Research Center of Baghiyatallah University
Full name of responsible person
Yunes Panahi
Position
PhD of clinical pharmacy
Other areas of specialty/work
Street address
Baghiyatallah University, Mollasadra street
City
Tehran
Postal code
Phone
+98 21 8821 1524
Fax
Email
yunespanahi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Research Center of Baghiyatallah University
Full name of responsible person
Yunes Panahi
Position
PhD of clinical pharmacy
Other areas of specialty/work
Street address
Baghiyatallah University, mollasadra street
City
Tehran
Postal code
Phone
+98 21 8821 1524
Fax
Email
yunespanahi@yahoo.com
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