Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment the effect of Clonidine and Dextromethorphan on cold pain threshold in healthy volunteers

Protocol summary

Summary

The goal of this study is to determine the threshold of pain from the cold after taking certain doses of Clonidine, Dextromethorphan and placebo. This study in third phase clinical trials, non random, double blind (Blind examiner and participant by coding pocket of drugs in secret by the supervisor), control with placebo, single central, cross-over, consists of 35 members of staff and students of Imam Khomeini hospital who volunteer picked through a public call on a hospital bulletin board. The main inclusion criteria are: physical and mental health, age 18-45 years and exclusion criteria are: pregnancy and any disease is affecting pain threshold. Evaluation of pain threshold in all stages will be base on the duration of time that a hand is kept in cold water. Participants are requested to immerse their hand in two liters of cold water and ice 0-2 °C and when they feel pain and they can't tolerate cold water, pull out their hand from water. All the pain thresholds of volunteers in 5 stages are measured: Before pharmacological interventions and after taking 0.2 mg Clonidine, 0.3 mg/kg Dextromethorphan, placebo, 0.2 mg Clonidine with 0.3 mg/kg Dextromethorphan and after necessary time to reach peak effect. Considering half lives of Clonidine and Dextromethorphan tablets and elimination the effects of drugs from body after 5 half-lives, wash out period and intervals of tablets taking and the measurement of pain thresholds is 10 days. Pharmacological interventions will be same for all volunteers in each stage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020826447N1**
Registration date: **2016-05-12, 1395/02/23**
Registration timing: **na**
Last update:
Update count: **0**

Registration date

2016-05-12, 1395/02/23

Registrant information

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Recruitment status

Not enough for processing

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of Clonidine and Dextromethorphan on cold pain threshold in healthy volunteers

Public title

The effect of Clonidine and Dextromethorphan on cold pain threshold

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Complete physical and mental health; Informed consent to participate in the study; 18-45 years of age; No cigarette smoking and coffee use; No history of taking anti depressant and analgesic medications. Exclusion Criteria: Acute or chronic pain; Pregnancy; Gastrointestinal bleeding; Renal or liver disease; Asthma; Diabetes; Hyper tension; Mental and, or neurological disease; Hyper sensitivity to Clonidine and Dextromethorphan.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, the corner of Qods St, Keshvarz Blvd, Tehran

City

Tehran

Postal code

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.TUMS.REC.1394.2127

Health conditions studied

1

Description of health condition studied

The pain induced by cold

ICD-10 code

T33.5

ICD-10 code description

Superficial frostbite of wrist and hand

Primary outcomes

1

Description

Cold pain threshold

Timepoint

Before interventions, First day(After taking pills available in packet No.1), 11th day(after taking pills available in packet No.2), 21th day(After taking pills available in packet No.3), 31th day(After taking pills available in packet No.4), 41th day(After taking pills available in packet No.5).

Method of measurement

The maximum storage time (in minutes) in a mixture of water and ice.

Secondary outcomes

empty

Intervention groups

1

Description

All the participants will take Clonidine and Dextromethorphan and Placebo tablets (Considering a 10 day wash-out period for each dose of medication). Clonidine tablet, 0.2 mg single dose, once during the test, 1.5 hours before test. Dextromethorphan tablet, 0.3 mg/kg single dose, once during the test, 30 minutes before test. Placebo, once during test, 1 hours before test. Clonidine tablet, 0.2 mg single dose with Dextrometorphan tablet, 0.3 mg /kg single dose, once during test, 1 hours before test.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr.Amirhossein Orandi

Street address

Imam Khomeini hospital, end of Keshavarz Blvd, Tehran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Student's Scientific Research Center of Tehran University of Medical Sciences
Full name of responsible person
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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
Student's Scientific Research Center of Tehran University of Medical Sciences
Proportion provided by this source
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

2

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Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr.Amirhossein Orandi
Proportion provided by this source
Public or private sector
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Domestic or foreign origin
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Category of foreign source of funding
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Country of origin
Type of organization providing the funding
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Person responsible for general inquiries

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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