

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of ondansetron efficacy in reducing capsaicin-induced inflammation: a randomized crossover clinical trial.

Protocol summary

Study aim

Determining the effect of ondansetron in reducing capsaicin-induced inflammation

Design

Clinical trial with crossover groups, double-blind, randomized, phase 3 on 25 patients, rand function of Excel software used for randomization.

Settings and conduct

This project was carried out at Shahid Sadoughi Hospital in Yazd. the participants periodically in one of the four groups of formulations containing a fixed amount of 0.075% of capsaicin and different amounts of ondansetron (zero, 0.75%, 1.31% and 1.88 percent) are placed

Participants/Inclusion and exclusion criteria

Volunteers who are older than 18 years, do not have allergy to capsaicin, and are not pregnant or lactating. Exclusion criteria are: sensitivity to capsaicin, pregnancy, breastfeeding and occurrence of side effects during the study.

Intervention groups

In order to investigate the effect of ondansetron in reducing the inflammation caused by capsaicin, the participants periodically in one of the four groups of formulations containing a fixed amount of 0.075% of capsaicin and different amounts of ondansetron (zero, 0.75%, 1.31% and 1.88 percent) are placed

Main outcome variables

Burning intensity caused by capsaicin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N11**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **retrospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

behrooz heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8699

Email address

b.heydari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ondansetron efficacy in reducing capsaicin-induced inflammation: a randomized crossover clinical trial.

Public title

The effect of ondansetron in reducing capsaicin inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years Insensitivity to capsaicin
Exclusion criteria:
Hypersensitivity to capsaicin Pregnancy Breastfeeding
Occurrence of side effects during the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants were randomly and periodically in one of the four groups of formulations containing a fixed amount of 0.075% of capsaicin and different amounts of ondansetron (zero (A), 0.75% (B), 31.1% (C) and 1.88 percent (D)). In order to randomize, the block random allocation method was used. In this study, 5 blocks of 5 were considered. The permutations produced include the letters C, B, A and D are repeated. These permutations were produced with the help of Random allocation software version 1. For this purpose, the list prepared by the software is from number 1 to 25, which are placed in 5 blocks of five. The implementation of this software output will give the first qualified person number 1 and the last person will receive number 25.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patients, the clinical caregiver and the outcome assessor were not aware of the type of medication the patients received. The patients received the medications in the same packaging

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Medicine- Shahid Sadoughi University of

Medical Sciences

Street address
Shahid Sadoughi University of Medical Science,
Shohadaye Gomnam Blvd, Alem Sq

City
Yazd

Province
Yazd

Postal code
8915173143

Approval date
2020-01-14, 1398/10/24

Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.265

Health conditions studied

1

Description of health condition studied
Inflammation caused by capsaicin

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity and duration of capsaicin-induced burning
Timepoint
Days 1, 2 and 3
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Volunteers use a cream containing 0.075% capsaicin and 0.75% ondansetron (manufactured in Yazd Faculty of Pharmacy) for 3 days and 4 times a day on their knees.
Category
Treatment - Drugs

2

Description
Intervention group 2: Volunteers use a cream containing 0.075% capsaicin and 1.31% ondansetron (manufactured in Yazd Faculty of Pharmacy) for 3 days and 4 times a day on their knees.
Category
Treatment - Drugs

3

Description

Intervention group 3: Volunteers use a cream containing 0.075% capsaicin and 1.88% ondansetron (manufactured in Yazd Faculty of Pharmacy) for 3 days and 4 times a day on their knees.

Category

Treatment - Drugs

4

Description

Control group: Volunteers use a cream containing 0.075% of capsaicin and no ondansetron (manufactured in Yazd Faculty of Pharmacy) for 3 days and 4 times a day on their knees.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Behrooz Heydari

Street address

Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd.

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Phone

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Email

b.heydari@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abarghouei

Street address

Shahid Sadoughi University of medical sciences, Shohadaye Gornan Blvd, Alem Sq

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abargouei@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Position

Assistant professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After nonrecognition, all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document

Request your information by email. The data will be sent after a week.

Comments