Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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 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