

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Study to Evaluate Efficacy and Safety of Sumatriptan and Ondansetron for the Treatment of Intrathecal Fentanyl-Induced Pruritus in Patients Undergoing Spinal Anesthesia

Protocol summary

Summary

This randomized, double-blind, and placebo-controlled study (phase 1-2) is done at ValiAsr and Imam Khomeini hospitals. The aim of this study is to investigate the efficacy and safety of sumatriptan vs. ondansetron and placebo for the treatment of intrathecal fentanyl-induced pruritus. Participants and investigators are blinded through the study. Participants are chosen among the patients with intrathecal fentanyl-induced pruritus in an elective gynecologic, urologic or general surgery. Seventy-five ASA physical status I-II and conscious patients of both sexes between the ages of 18 and 65 years suffering from fentanyl-induced itch are included in this study. While patients who have itch secondary to conditions other than intrathecal fentanyl, the history of cardiovascular diseases, or uncontrolled serious systemic disorders are excluded. Then the participants are randomly divided into sumatriptan (6mg), ondansetron (8mg) or placebo groups by block randomization. The primary outcome is comparing the mean of visual analogue scale (VAS) score for itch and the dynamic pruritus score (DPS) over 90 minutes between treatment groups. Likewise, the incidence of side effects, pain VAS intensity scale and nausea 4-point rating score are assessed. Finally, the patients will be asked about their satisfaction with treatment of pruritus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030432871N1**

Registration date: **2017-07-24, 1396/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

Name

Ahmad Reza Dehpour

Name of organization / entity

Experimental Medicine Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 3652

Email address

dehpoura@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Brain and Spinal Cord Injury Research Center,
Neuroscience Institute, Tehran University of Medical
Sciences, Tehran, Iran

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study to Evaluate Efficacy and Safety of Sumatriptan and
Ondansetron for the Treatment of Intrathecal Fentanyl-
Induced Pruritus in Patients Undergoing Spinal
Anesthesia

Public title

Sumatriptan and Ondansetron in Treatment of Spinal anesthesia-Induced Pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Males or females who are at least 18 years and no more than 65 years of age; Candidate for urologic, gynecologic or general surgery with spinal anesthesia, Intrathecal fentanyl-induced pruritus; Giving informed consent; ASA physical status I-II; GCS equal to 15; Exclusion criteria: Pruritus secondary to a pruritic skin disease or systemic disorder; Topical or systemic treatments which may affect the intensity of itch; History of cardiovascular diseases, or uncontrolled serious systemic disorders; Currently is taking a monoamine oxidase inhibitor (MAOI) or has taken a MAOI within the 2 weeks prior to screen; Currently is taking an ergotamine-containing medication; Being pregnant, actively trying to become pregnant or breastfeeding; Alcohol or substance abuse

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg, Poursina st.

City

Tehran

Postal code**Approval date**

2017-04-03, 1396/01/14

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2007

Health conditions studied**1****Description of health condition studied**

Intrathecal fentanyl-induced pruritus

ICD-10 code

L29.8

ICD-10 code description

Other pruritus

Primary outcomes**1****Description**

Itch intensity

Timepoint

0, 5, 10, 20, 30, 60 and 90 minutes after the intervention

Method of measurement

VAS score and DPS score

Secondary outcomes**1****Description**

Pain intensity

Timepoint

15, 30, 60 and 90 minutes after the intervention

Method of measurement

VAS score

2**Description**

Nausea, vomiting intensity

Timepoint

15, 30, 60 and 90 minutes after the intervention

Method of measurement

4-point rating score for nausea and vomiting

3**Description**

Side effects

Timepoint

5, 10, 20, 30, 60 and 90 minutes after the intervention

Method of measurement

Occurrence of any type of medical complications from clinical evidence and patient complaints

4**Description**

Treatment satisfaction

Timepoint

90 minute after the intervention
Method of measurement
Asking the patients

Intervention groups

1

Description

Intervention/Control 1: Sumatriptan 6mg/0.5ml statdose subcutaneous injection + Placebo in volume of 4ml statdose IV injection

Category

Treatment - Drugs

2

Description

Intervention/Control 2: Placebo in volume of 0.5ml statdose subcutaneous injection + Ondansetron 8mg/4ml statdose IV injection

Category

Treatment - Drugs

3

Description

Intervention/Control 3: Placebo in volume of 0.5ml statdose subcutaneous injection + Placebo in volume of 4ml statdose IV injection

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Nazgol-Sadat Haddadi

Street address

Chamran highway, Bagherkhan St., Imam Khomeini Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital

Full name of responsible person

Nazgol-Sadat Haddadi

Street address

End of the Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Brain and Spinal Cord Injury Research Center

Full name of responsible person

Dr. Ahmad-Reza Dehpour

Street address

Chamran highway, Bagherkhan St., Imam Khomeini Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Brain and Spinal Cord Injury Research Center

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

Experimental Medicine Research Center, Tehran University of Medical Sciences

Full name of responsible person

Ahmad-Reza Dehpour

Position

Full professor

Other areas of specialty/work

Street address

Dept. of Pharmacology, School of Medicine, Tehran University of Medical Sciences, Poorsina St., Enghelab Ave.

City

Tehran

Postal code

Phone

+98 21 8897 3652

Fax

Email

Dehpoura@sina.tums.ac.ir; Dehpour@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Experimental Medicine Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Nazgol-Sadat Haddadi

Position

MD-MPH

Other areas of specialty/work**Street address**

Dept. of Pharmacology, School of Medicine, Tehran
University of Medical Sciences, Poorsina St., Enghelab
Ave.

City

Tehran

Postal code**Phone**

+98 21 8897 3652

Fax**Email**

nazgolhadadi@gmail.com

Web page address

MD-MPH

Other areas of specialty/work**Street address**

Dept. of Pharmacology, School of Medicine, Tehran
University of Medical Sciences, Poorsina St., Enghelab
Ave.

City

Tehran

Postal code**Phone**

+98 21 8897 3652

Fax**Email**

nazgolhadadi@gmail.com

Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Experimental Medicine Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Nazgol-Sadat Haddadi

Position