

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Protocol summary

Study aim

Comparison the effect of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Design

This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 60 pregnant women candidates for elective cesarean section.

Settings and conduct

In this interventional study, 60 pregnant women candidates for elective cesarean section in Yas hospital are selected by convenience sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all pregnant women who are candidates for elective cesarean section with spinal anesthesia. Exclusion criteria: patients with sensitivity to Tramadol or Ondansetron, Emergency cesarean section, and Contraindications to spinal anesthesia.

Intervention groups

After performing spinal anesthesia for the patient, for the intervention, 4 mg of Ondansetron is injected by the anesthesiologist as an intravenous bolus and for the control group, 0.6 mg/kg of Tramadol is injected by the anesthesiologist as an intravenous bolus.

Main outcome variables

The patient's shivering and pain after the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055225N3**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Khadijeh Adabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 8217

Email address

kh_adabi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of Tramadol and Ondansetron in controlling pain and shivering in pregnant women candidate for cesarean section

Public title

The controlling pain and shivering in pregnant women candidate for cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All pregnant women are candidates for elective cesarean section with spinal anesthesia

Exclusion criteria:

Sensitivity to Tramadol or Ondansetron Emergency cesarean section Contraindications to spinal anesthesia include intracranial space lesions, systemic or spinal anesthesia puncture site infection, and coagulation disorders

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 30 letters A and 30 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (intervention) or B (control) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed double-blind, the participants and the researcher do not know the type of treatment. For each patient, the appropriate study drug was prepared and diluted (clear and transparent solution) to a volume of 4 ml (in a 5 ml syringe).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina Ave., Qods Blvd.

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Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.478

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O75.82

ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description

The patient's shivering

Timepoint

Once, after delivery

Method of measurement

Using Tsai and Chu criteria

2

Description

The amount of patient's pain

Timepoint

Once, after delivery

Method of measurement

Using VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After performing spinal anesthesia for the patient, 4 mg of Ondansetron is injected by the anesthesiologist as an intravenous bolus.

Category

Treatment - Drugs

2

Description

Control group: After performing spinal anesthesia for the patient, 0.5 mg/kg of Tramadol is injected by the anesthesiologist as an intravenous bolus.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yas hospital

Full name of responsible person

Khadijeh Adabi

Street address

Yas hospital, Next to the Sarv St., North Nejatollahi Str., Karim Khan Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

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Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Adabi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The anonymous study data is potentially shareable.

When the data will become available and for how long

After the manuscript is published.

To whom data/document is available

No limitations.

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Khadijeh Adabi, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Khadijeh Adabi

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

Any request must be sent by e-mail with its proposal to Dr. Khadijeh Adabi.

Comments