Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of oral Tramadol in prevention and treatment of Intra & post-operative shivering in inguinal surgery by spinal anesthesia

Protocol summary

Study aim

Evaluation of the efficacy of oral tramadol in preventing shivering as an complication of the anesthesia, before and during elective surgery.

Design

The clinical trial has two groups. All patients are candidates for elective inguinal surgery with spinal anesthesia. The study is phase 3. 200 patients will be selected and divided into intervention and comparison group of 100. This is a double blinded study and SPSS was used for randomization.

Settings and conduct

The study site is Ayatollah Rouhani Hospital in Babol. The study is performed in the way of oral medication or placebo, two hours before surgery, then patients' clinical response during and after surgery will be collected and recorded in forms. The researcher and clinical caregiver are blinded. Contents and packaging of a medicine or placebo similar in shape, color, size, and can only be identified to statistician by random four-digit numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 70 years Classes one and two ASA Elective surgery Inguinal surgery Spinal anesthesia No drug addiction Exclusion criteria: Patient dissatisfaction with spinal anesthesia ASA class three or more Emergency surgery Drug addiction Recent history of nausea and vomiting History of respiratory depression

Intervention groups

Two hours before the operation, each patient given a 50 mg tramadol tablet (case group) with 150 cc of water or a placebo Which is folic acid tablet with 150 cc of water (control group), respectively. Patients then enter the operating room and begin to surgery according to the previous surgical speculation. It should be noted that all patients will be monitored for hemodynamic and respiratory status immediately after receiving oral tramadol in a dose of 50 mg or placebo.

Main outcome variables

If tramadol is effective before surgery, the incidence of chills will be reduced initially before surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044907N2**
Registration date: **2021-05-02, 1400/02/12**
Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**
Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

seyed hossein hamidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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a.hamidi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of oral Tramadol in prevention and treatment of Intra & post-operative shivering in inguinal surgery by spinal anesthesia

Public title
The effect of oral Tramadol in prevention and treatment of shivering during and after surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 18 to 70 years Classes one and two ASA Elective surgery Inguinal surgery Spinal anesthesia non opium addict

Exclusion criteria:
Patient refuse to spinal anesthesia Clinical ASA class three or more Emergency surgery indications Any substance addiction History of allergies to tramadol or other Opiates History of preoperative shivering History of respiratory depression

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple random method with individual units will be used. The patients are divided into two groups of 100 intervention and control using a table of random numbers generated by SPSS. The table of numbers produced will be available only to the statistician, and the researcher, clinical caregiver, and patient will not be aware of the contents of the medication package. If the patient enters the intervention group, they will receive a packet of medicine and if he enters the control group, they will receive a placebo. Medication Envelope and Tablet The drug or placebo is exactly the same in shape, size, envelope size, and pill size, and only the random numbers on the envelope are written on them. Neither the physician nor the patient knows which patient is receiving medication or placebo based on random numbers on each envelope. Only a statistician can access the random number table to find out which patient has received medication or placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, only the statistician knows the contents of the drug or placebo package, and researchers, patients, and clinical caregivers are blind to the data and prescription of the drug or placebo. After explaining to patients and obtaining informed consent, they will be explained that they may be in any of the groups receiving medication or placebo. The selection of patients to be in the group of receiving medication or placebo will be done by random software and random numbers, which is done by a statistician. The statistics expert has provided 100 envelopes containing unnamed and randomly numbered drugs, and 100 envelopes containing placebo and encoded with random numbers. The medicine and the pharmacopoeia and their packaging will be completely similar in shape, color and size. Anesthesiologists and health care providers in the operating room are blind to the contents of the envelope for medication or placebo, and only after entering the envelope code in the data collection form, they prescribe the contents to the patient, followed by cardiovascular and respiratory monitoring of all patients equally.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Babol University of Medical Sciences

Street address
Ganj Afrooz St., University Square

City
Babol

Province
Mazandaran

Postal code
47176-41367

Approval date
2020-11-14, 1399/08/24

Ethics committee reference number
IR.MUBABOL.REC.1399.366

Health conditions studied

1

Description of health condition studied
peri operative shivering

ICD-10 code
R68.83

ICD-10 code description
Chills (without fever)

Primary outcomes

1

Description
Shivering during and after surgery
Timepoint
At beginning, 5، 10، 15، 20، 30، 45، 60، 75، 90، 120 minutes after beginning of surgery
Method of measurement
Researcher's observation for the incidence and severity of shivering based on a comparison of Crassell ratings

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving the drug receive a 50 mg tablet of oral tramadol made by Caspian Pharmaceutical Company, single dose and 2 hours before the start of elective surgery in the inguinal area by spinal anesthesia.
Category
Treatment - Drugs

2

Description
Control group: Patients receiving placebo, receiving vitamin supplement in the form of 1 mg tablets of oral folic acid, made by Rooz Daroo Pharmaceutical Company, are single dose and 2 hours before the start of elective surgery in the inguinal area by spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital of Babol
Full name of responsible person
Seyed Hossein Hamidi M.D.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Seyed Hossein Hamidi M.D.
Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable