Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the efficacy of different doses of adjuvant perineural tramadol to 0.25% bupivacaine in prolongation of postoperative analgesia in arthroscopic shoulder surgeries under interscalene block

Protocol summary

Study aim
Evaluating the effect of perineural tramadol on postoperative analgesia duration

Design
This phase 3 study has been designed as a double-blind randomized clinical trial. The sample size is 60 and patients are divided into 3 groups, one group is for control and 2 groups are for the intervention.

Settings and conduct
The place for this study is Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, orthopedic operating room. One of the nurse assistants allocates the patients randomly into a group. The clinical nurse, the patient, the clinical evaluator assistant, and the anesthesiologist are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 years and above candidate for arthroscopic shoulder surgery in full cognition state. Exclusion criteria: Body mass index 40 or more, History of seizure, History of allergic reactions to drugs in this study patients' refusal, pregnancy or breastfeeding, ASA class III or more.

Intervention groups
Control group: receives bupivacaine 0.25% and epinephrine solution in a total volume of 15 milliliters in interscalene block؛ Intervention group 1: Tramadol 100 milligrams is added to the first solution؛ Intervention group 2: Tramadol 200 milligrams is added to the first solution.

Main outcome variables
Pain score in recovery؛ Pain score in the ward at 4, 8, 12, 18, and 24 hours post nerve block؛ analgesic requirements in recovery؛ opioid requirements in the ward during first postoperative day؛ time to peak postoperative pain scores.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140427017455N5**
Registration date: **2019-03-25, 1398/01/05**
Registration timing: **retrospective**

Last update: **2019-03-25, 1398/01/05**
Update count: **0**

Registration date
2019-03-25, 1398/01/05

Registrant information

Name
Amir Poya Zanjani
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Tehran University Of Medical Science, investigation unit

Expected recruitment start date
2016-04-03, 1395/01/15

Expected recruitment end date
2017-10-07, 1396/07/15

Actual recruitment start date
2016-06-04, 1395/03/15

Actual recruitment end date
2017-12-06, 1396/09/15

Trial completion date
2017-12-21, 1396/09/30

Scientific title
Comparison of the efficacy of different doses of adjuvant perineural tramadol to 0.25% bupivacaine in prolongation of postoperative analgesia in arthroscopic shoulder surgeries under interscalene block

Public title
Effects of adding different doses of tramadol to bupivacaine solution for brachial plexus block on postoperative analgesia duration after arthroscopic shoulder surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidate for Shoulder arthroscopic surgery Age 18 years or more ASA class I-II Intact cognition and contiousness

Exclusion criteria:
Patient refusal Contraindication for drug infiltration History of Allergic reactions to drug used in this study Contraindication for intrscalene block Contraindication for tramadol administration Opioid abuse history Pregnancy or baby breast feeding Chronic pain syndromes Any neurological problem in the same side upper limb History of epilepsy Body mass index 40 or higher

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple, Unit of randomization: individual, Tools of randomization: Software, Allocation concealment: by the same software

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are blind The researcher who injects the solution receives a prepared solution, therefore the researcher is blind. The care provider nurses in the operating room and the recovery room are blind. The research team member who evaluates the patient is also blind.

Placebo
Not 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 Scienses

Street address
Qods St., Keshavarz Blvd.

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Tehran

Province
Tehran

Postal code
1417653761

Approval date
2016-05-28, 1395/03/08

Ethics committee reference number
IR.TUMS.REC.1395.2638

Health conditions studied

1

Description of health condition studied
post shoulder arthroscopic surgery analgesia duration

ICD-10 code
Y45.0

ICD-10 code description
Opioids and related analgesics

Primary outcomes

1

Description
Postoperative pain scores at recovery

Timepoint
10 minutes after patient's admission to recovery

Method of measurement
Visual Analogue Scale VAS

2

Description
Postoperative Pain Scores in the ward

Timepoint
4, 8, 12, 18 and 24 hours post brachial plexus block

Method of measurement
Visual Analogue Scale VAS

3

Description
Time to maximum postoperative pain score
Timepoint
during the first postoperative 24-hours
Method of measurement
Visual Analogue Scale VAS

4

Description
Time to first rescue analgesic dose
Timepoint
During the first postoperative day
Method of measurement
First analgesic injection in ward based on patient's medical records

5

Description
Total administered opioid during the first postoperative 24-hours
Timepoint
during the first postoperative 24-hours
Method of measurement
total administered opioid from admission to ward to 24 hours post plexus block, based on medical records

6

Description
Total administered opioid in the recovery
Timepoint
During the recovery period
Method of measurement
total administered opioid during the recovery based on the patient's medical records

Secondary outcomes

1

Description
Nausea
Timepoint
Once at the end of surgery, and then at the end of the first post operative 24-hour
Method of measurement
Patients' medical records

2

Description
Vomiting
Timepoint
Once at the end of surgery, and then at the end of the first post operative 24-hour
Method of measurement
Patients' medical records

3

Description
Seizure
Timepoint
Once at the end of surgery, and then at the end of the first post operative 24-hour
Method of measurement
Patients' medical records

Intervention groups

1

Description
Intervention group 1: Perineural injection of 0.25% bupivacaine and 1/200000 epinephrine with 100 mg tramadol in 15 milliliters volume in interscalene block
Category
Treatment - Drugs

2

Description
Intervention group 2: Perineural injection of 0.25% bupivacaine and 1/200000 epinephrine with 200 mg tramadol in 15 milliliters volume in interscalene block
Category
Treatment - Drugs

3

Description
Control group: Perineural injection of 0.25% bupivacaine and 1/200000 epinephrine in 15 milliliters volume in interscalene block
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedics operating room of Tehran Imam Khomeini Complex Hospital
Full name of responsible person
Amir Poya Zanjani
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Web page address
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Sponsors / Funding sources

1

Sponsor
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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
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available