Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Clinical trial on incremental and low dose remifentanil effect on acute postoperative pain in recovery room after shoulder surgeries

Protocol summary

Summary

In current prospective randomized double-blinded clinical trial, 20 patients, candidate for shoulder surgery, with grade I or II of American society of anesthesiology (ASA), will be evaluated. Patients with history of uncontrollable chronic pain and pregnancy will be excluded. Subsequent to admission in recovery ward, patients will be randomly assigned to study groups and analgesia protocol will be administered. Right after preparation of required monitoring, pain score will be determined and recorded using pain severity scoring scale. Afterward, subsequent to pain onset in patients, analgesia will be provided via routine recovery (using morphine) in control group and using incremental and low dose remifentanil in intervention group. In control group, routine recovery will provided using 0.1 mg/kg morphine administration in divided doses. In intervetion group, diluted remifentanil solution including 10 micrograms per milliliter of remifentanil will be infused 1 milliliter per 20 seconds till pain relief. Individual recording the variables will be blinded to treatment type. Variables such as pain severity, analgesia onset time, analgesia duration, patient request to receive analgesics, apnea incidence, other adverse effects (including nausea and vomiting, bradycardia, hypotension, muscle spasm, pruritus), pain recurrence time and amount of administered drugs will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050126328N4**
Registration date: **2017-06-06, 1396/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name
Masoud Parish
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 3385 5842
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parishm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz university of medical sciences,

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on incremental and low dose remifentanil effect on acute postoperative pain in recovery room after shoulder surgeries

Public title

Remifentanil effect on shoulder surgery postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients candidate to undergo shoulder surgery; aged between 20 and 60 years old; Class I or II according to ASA classification. Exclusion criteria: history of uncontrollable chronic pain; history of allergy to analgesics; history of psychotropic drugs consumption; recent use of analgesics; operation time more than 2 hours; pregnant and breastfeeding women.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be performed using Randlist 1.2. software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz university of medical sceinces, Daneshgah square

City
Tabriz

Postal code

Approval date
2016-08-29, 1395/06/08

Ethics committee reference number
IR.TBZMED.REC.1395.665

Health conditions studied

1

Description of health condition studied
Shoulder fracture postoperative pain

ICD-10 code
S43

ICD-10 code description
Dislocation, sprain and strain of joints and ligaments of shoulder girdle

Primary outcomes

1

Description
Duration of analegsia onset

Timepoint
Postoperative recovery

Method of measurement
Questionnaire

2

Description
Patients pain severity after shoulder surgery during recovery

Timepoint
In admission to recovery room and discharge from the recovery

Method of measurement
Using visual analogue scale

Secondary outcomes

1

Description
administered remifentanil dosage amount

Timepoint
During admission to recovery

Method of measurement
Questionnaire

2

Description
nausea and vomiting due to remifentanil injection

Timepoint
During admission to recovery

Method of measurement
Questionnaire

3

Description
hypotension due to remifentanil injection

Timepoint
During admission to recovery

Method of measurement
Questionnaire

4

Description
bradycardia due to remifentanil injection

Timepoint

During admission to recovery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Diluted remifentanil solution including 10 micrograms per milliliter will be infused 1 milliliter each 20 minutes, till complete analgesia onset.

Category

Treatment - Drugs

2

Description

Control group: 0.1 milligram per kilogram morphine will be administered in divided doses, till complete analgesia onset.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Dr. Masoud Parish

Street address

Shohada hospital, Golshahr street, Yaxchian, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of medical sceinces, Daneshgah square

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Masoud Parish

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Contact

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Full name of responsible person

Dr. Masoud Parish

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Other areas of specialty/work
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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