

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Preventive effect of sub acromial bupivacaine injection on acute pain after arthroscopic rotator cuff repair surgery

Protocol summary

Study aim

Determining the preventive effect of sub acromial bupivacaine injection on acute pain after arthroscopic rotator cuff repair surgery

Design

A randomized, double-blind, randomized clinical trial are carried out on 64 patients.

Settings and conduct

This study will be performed in Shahid Rahnemoun Hospital in Yazd in 2021 . A randomized, double-blind, randomized clinical trial are carried out on 64 patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of rotator cuff rupture clinically and MRI result. Also people who have the ability to read, understand and record information. Exclusion criteria: Patients with corrective or secondary surgery, patients with a history of trauma in the last 3 months, patients who have other surgeries in addition to rotator cuff repair.

Intervention groups

The first group is injected with bupivacaine and epinephrine one hour before the operation and the second group is injected with the same drugs after the operation.

Main outcome variables

Post-operative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161225031559N5**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Seyed Hossein Saeed-Banadaky

Name of organization / entity

Shahid Sadoughi Medical University

Country

Iran (Islamic Republic of)

Phone

+98 35 3626 0001

Email address

saeed@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preventive effect of sub acromial bupivacaine injection on acute pain after arthroscopic rotator cuff repair surgery

Public title

The effect of pre-operative shoulder analgesia on decrease post-operative pain after rotator cuff repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Diagnosis of rotator cuff rupture clinically and MRI result. Conscious consent of the participants, Patients who are able to read and write. Exclusion criteria: Exclusion criteria: Patients with corrective or secondary surgery, patients with a history of trauma in the last 3 months, patients who have other surgeries in addition to rotator cuff repair, Patients who have mental health problems. Age From 30 years old to 80 years old Gender Both	Street address Bahonar square City Yazd Province Yazd Postal code 8916978477 Approval date 2020-05-11, 1399/02/22 Ethics committee reference number IR.SSU.MEDICINE.REC.1399.014
Phase N/A Groups that have been masked - Care provider - Investigator - Data analyser	Health conditions studied <u>1</u> Description of health condition studied Arthroscopic rotator cuff repair ICD-10 code S46.0
Sample size Target sample size: 64 Randomization (investigator's opinion) Randomized Randomization description For randomization, the blanced block randomization method is used to generate quadruple blocks. After the randomization sequence is prepared by the methodologist and using the sealedenvelope online site, the generated sequence will be provided to a technician. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is determined. Based on the randomly selected envelope, the patient is placed in group (A) preoperative injection or group (B) postoperative injection. Blinding (investigator's opinion) Double blinded Blinding description evaluators and statistical analysts are unaware. The data are written in code A and B in which the analyst and evaluator do not interfere. Placebo Not used Assignment Parallel Other design features	ICD-10 code description Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder Primary outcomes <u>1</u> Description Post-operative pain score Timepoint Pain before and after surgery and up to 3 days after surgery Method of measurement Questionnaire, Visual Analogue Scale
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee ofEthics committee of Shahid Sadoughi University of Medical Sciences	Secondary outcomes <u>1</u> Description hours of sleep Timepoint Pre-operative and post-operative Method of measurement questionnaire, The sleep time is entered into the clock in the questionnaire. Intervention groups <u>1</u> Description First intervention group: 20 cc of bupivacaine, 0.25% of 40 micrograms of epinephrine will be injected into the sub acromial space space after surgery. Category Treatment - Drugs

2

Description

Second intervention group: 20 cc of bupivacaine, 0.25% of 40 micrograms of epinephrine will be injected into the sub acromial space one hour after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mojibian Hospital

Full name of responsible person

Amin Adeli Mirzaei

Street address

Kashani Street

City

Yazd

Province

Yazd

Postal code

8915635796

Phone

+98 35 3624 0061

Email

info@mojibian.ir

2

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Amin Adeli Mirzaei

Street address

Ebn Sina Street, Shahid Ghandi Blvd

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4009

Email

sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Houshang Mehrparvar

Street address

bahonar square

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3726 3733

Email

ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Amin Adeli Mirzaei

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Farokhi Street

City

Yazd

Province

Yazd

Postal code

8913814396

Phone

+98 35 3312 2002

Email

amin_adeli21@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Houssien Saeed-Banadaky

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Farokhi street

City

Yazd

Province

Yazd

Postal code

8913814396

Phone

+98 35 3312 2002

Email

saeed@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Adeli Mirzaei

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Farokhi street

City

Yazd

Province

Yazd

Postal code

8913814396

Phone

+98 35 3312 2002

Email

amin_adeli121@yahoo.com

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