

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Dexamethasone Compared with Dexmedetomidine as an adjuvant to Bupivacaine for Supraclavicular Brachial Plexus Block

Protocol summary

Study aim

Dexamethasone Compared with Dexmedetomidine as an adjuvant to Bupivacaine for Supraclavicular Brachial Plexus Block

Design

Double Blinded Randomized Clinical Trial

Settings and conduct

In the operating theater of Chamran hospital ,patients in the intervention group one receive 24 ml of bupivacaine(bupivacaine,Mylan,A.S.A, France)(0.5%) plus 1 ml of dexamethasone (4 mg) for supraclavicular block. In the second group, patients receive 24 ml of bupivacaine (bupivacaine,Mylan,A.S.A, France)(0.5%) plus 0.5 ml of doxedemotomidine (50 µg) for supraclavicular block.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Age 21 to 60 years old , Fractures of the forearm surgeries under supraclavicular plexus block.

Exclusion Criteria: Heart disease ,Patients with high blood pressure, Bradycardia ,Hyperthyroidism ,Cardiac Blocks of Grade 1,2,3 ,Use of adrenoceptor agonist and antagonist ,Peripheral neuropathy ,pregnant women, Patients who are addicted to narcotics and stimulant drugs ,Patients susceptible or allergic to the drugs , Coagulation disorders, Local infections, Patient refusal

Intervention groups

Patients in the intervention group one receive 24 ml of bupivacaine(bupivacaine,Mylan,A.S.A, France)(0.5%) plus 1 ml of dexamethasone (4 mg) for supraclavicular block. In the second group, patients receive 24 ml of bupivacaine (bupivacaine,Mylan,A.S.A, France)(0.5%) plus 0.5 ml of doxedemotomidine (50 µg) for supraclavicular block.

Main outcome variables

Duration of sensory block, Onset of the sensory block,Duration of the motor block,Onset of the motor block

General information

Reason for update

Due to several refereeing corrections at the time of registration, the expected recruitment start date has not been corrected in the last refereeing. Please, change expected recruitment start date two months later

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N84**
Registration date: **2019-07-30, 1398/05/08**
Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**

Update count: **1**

Registration date

2019-07-30, 1398/05/08

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-15, 1398/06/24

Expected recruitment end date

2019-10-29, 1398/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dexamethasone Compared with Dexmedetomidine as an adjuvant to Bupivacaine for Supraclavicular Brachial Plexus Block

Public title

Dexamethasone Compared with Dexmedetomidine as an adjuvant to Bupivacaine for Supraclavicular Brachial Plexus Block

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 21 to 60 years old Fractures of the forearm surgeries under supraclavicular plexus block

Exclusion criteria:

Heart disease Patients with high blood pressure Bradycardia Hyperthyroidism Cardiac Blocks of Grade 1,2,3 Use of adrenoceptor agonist and antagonist Peripheral neuropathy pregnant women Patients who are addicted to narcotics and stimulant drugs Patients susceptible or allergic to the drugs studied Coagulation disorders Local infections Patient refusal

Age

From **21 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups according to the table provided by Randomization.com and using Random permutations.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The same syringes containing 1 ml of dexamethasone or 1 ml of dexamethasone (0.5 cc dexamethasone diluted with half a cc distilled water), which are provided by a researcher, syringes are labeled only with the number, and the investigator dose not intervene in the Supraclavicular Brachial Plexus Block .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.SUMS.MED.REC.1396.121

Health conditions studied**1****Description of health condition studied**

Forearm bones fracture

ICD-10 code

M96.63

ICD-10 code description

Fracture of radius or ulna following insertion of orthopedic implant, joint prosthesis, or bone plate

Primary outcomes**1****Description**

Duration of sensory block

Timepoint

15 and 30 minutes after entering the recovery and 1,2,4,6,12,18,24 in the ward

Method of measurement

pinprick

2**Description**

Onset of the sensory block

Timepoint

At 0.1, 5, 10, 15, 20, 25 and 30 min after the injection of anesthetics

Method of measurement

pinprick

3

Description

Duration of the motor block

Timepoint

15 and 30 minutes after entering the recovery and
1,2,4,6,12,18,24 in the ward

Method of measurement

Bromage

4

Description

Onset of the motor block

Timepoint

15 and 30 minutes after entering the recovery and
1,2,4,6,12,18,24 in the ward

Method of measurement

Bromage

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group
one receive 24 ml of
bupivacaine(bupivacaine,Mylan,A.S.A, France)(0.5%)
plus 1 ml of dexamethasone (4 mg)(Caspian, Iran) for
supraclavicular block.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, patients receive
24 ml of bupivacaine (bupivacaine,Mylan,A.S.A, France)(
0.5%) plus 0.5 ml of doxedemotomidine
(Hospiar,INC,Lake Forest, USA) (50 µg) for
supraclavicular block.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Isaa Ahmadizadeh

Street address

Hafez Hospital, Chamran Hospital

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

namazi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research,7th floor of central
building of Shiraz University of Medical Sciences,
Zand

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

vcrdep@sums.ac

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Isaa Ahmadizadeh

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

isaahmadizadeh@yahoo.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Afshin Amini

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

afshinaminie@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Namazi Hospital, Namazi square

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@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