Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 adrenoreceptor 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 adrenoreceptor 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