Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of double tourniquet of arm and forearm in terms of the onset and duration of analgesia and pain of the tourniquet and the return of sensation and movement In the distal upper extremity surgery

Protocol summary

Study aim

Comparison of double tourniquet of arm and forearm in terms of the onset and duration of analgesia and pain of the tourniquet and the return of sensation and movement In the distal upper extremity surgery

Design

This study is clinical trial and double blind.70 patients candidate for orthopedic surgeries distal upper extremity Valiasr Hospital in Arak will inter this study.We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct

This study is clinical trial and double blind.70 patients candidate for orthopedic surgeries distal upper extremity Valiasr Hospital in Arak will inter this study.Outcome assessor and analyzer and participant don't aware from grouping.We check blood pressure, heart rate, oxygen saturation, pain, duration of sensory and motor block and use narcotic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both of gender, age 50 to 20 years ,ASA class 1 and 2 , duration of surgery is within 40 to 90 minutes , no pregnancy ,absence of Raynaud's disease and scleroderma ,lack of peripheral vascular disease, absence of methemoglobinemia and sickle cell disease ,lack of underlying illness ,no addiction ,lack of epilepsy ,lake of kidney failure Exclusion criteria:Patient dissatisfaction ,hemoglobin is less than 10 , consumers of calcium channel blockers or beta-blockers

Intervention groups

We will inject 40 milliliter of Lidocaine 0.5% plus 1microgram in kilogram Dexmedetomidin in the double-arm tourniquet arm. We will inject 20 milliliter of Lidocaine 0.5% plus 0.5 microgram in kilogram Dexmedetomidin in double tourniquet forearm.We inject through the dorsal vein of the organ that Surgery is performed on it.

Main outcome variables

blood pressure, heart rate, oxygen saturation, pain, duration of sensory and motor block , amount of narcotic use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N119**
Registration date: **2019-08-16, 1398/05/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-16, 1398/05/25**
Update count: **0**

Registration date

2019-08-16, 1398/05/25

Registrant information

Name
Fariba Farokhi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3222 2003
Email address
f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-04-08, 1399/01/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of double tourniquet of arm and forearm in terms of the onset and duration of analgesia and pain of the tourniquet and the return of sensation and movement In the distal upper extremity surgery

Public title
Comparison of two kine of tourniquet in terms of the onset and duration of analgesia and pain of the tourniquet and the return of sensation and movement In the distal upper extremity surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both gender Age 50 to 20 years ASA class 1 and 2 Duration of surgery is within 40 to 90 minutes No pregnancy Absence of Raynaud's disease and scleroderma Lack of peripheral vascular disease Absence of methemoglobinemia and sickle cell disease Lack of underlying illness No addiction Lack of epilepsy Lack of Kidney failure Distal upper extremity fracture
Exclusion criteria:
Patient dissatisfaction Hemoglobin is less than 10 Consumers of calcium channel blockers or beta-blockers
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer and participant don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2019-04-07, 1398/01/18
Ethics committee reference number
IR.ARAKMU.REC.1398.007

Health conditions studied

1

Description of health condition studied
Distal upper extremity fracture
ICD-10 code
S52
ICD-10 code description
Fracture of forearm

Primary outcomes

1

Description
Mean arterial blood pressure
Timepoint
Before intervention, 5, 10, 15, 20 minutes and then every 10 minutes to end of surgery and after emptying the tourniquet and recovery
Method of measurement
Barometer

2

Description
Heart rate
Timepoint
Before intervention, 5, 10, 15, 20 minutes and then every 10 minutes to end of surgery and after emptying the tourniquet and recovery
Method of measurement
Count

3

Description
Percent of oxygen saturation
Timepoint
Before intervention, 5, 10, 15, 20 minutes and then every 10 minutes to end of surgery and after emptying the tourniquet and recovery
Method of measurement
Pulse oximetry

4

Description
Duration of motor block
Timepoint
Every 5 minute
Method of measurement
Minute

5

Description
Duration of sensory block
Timepoint
Every 1minute
Method of measurement
Minute

6

Description
Mean use of narcotic
Timepoint
24 hour after surgery
Method of measurement
Milligram

7

Description
Pain
Timepoint
After filling the tourniquet, at the time of 15, 30 and 45 and every 15 minutes until the end of surgery
Method of measurement
Visual Analogue Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We will inject 40 milliliter of Lidocaine 0.5% (Daropakhsh Co) plus 1microgram in kilogram Dexmedetomidin (Ǝxir Co) in the double-arm tourniquet arm.A double-cuff tourniquet will be placed on the proximal arm, and the patient’s blood pressure will be measured before the inflation of the tourniquet. After exsanguination with an esmarch bandage, the cuff will be inflated to a pressure 150 mmHg above the systolic blood pressure.
Category
Treatment - Other

2

Description
Intervention group: We will inject 20 milliliter of Lidocaine 0.5% (Daropakhsh Co) plus 0.5 microgram in kilogram Dexmedetomidin (Exir Co) in double tourniquet forearm.It inject through the dorsal vein of the organ that Surgery is performed on it.A double-cuff tourniquet wiil be placed on the proximal arm, and the patient’s blood pressure will be measured before the inflation of the tourniquet. After exsanguination with an esmarch bandage, the cuff will be inflated to a pressure 150 mmHg above the systolic blood pressure.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
Valiasr hospital, Valiasr squre
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Esmaeel Moshiri
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Shirodi street, Valiasr square, Valiasr hospital
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
modir.he@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Hesamedin Modir
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Amirreza Modir
Position
Medicine student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Email
modir@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments