

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

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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 kind 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 committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

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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 (Ejir 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 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Valiasr hospital, Valiasr squire

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

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Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

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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