

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of local anesthetic injection site on the quality of intravenous block (bier block) in upper limb

Protocol summary

Study aim

Comparing the effect of local anesthetic injection site on the quality of intravenous block (bier block) in upper limb

Design

From a package of 70 cards, patients choose one card randomly. The letter A for the control group (Angiocath in the distal) and the letter B for the intervention group (Angiocath in the proximal). There are 35 patients in each group. Patients are then assigned to one of the intervention and control groups. Sampling continues in two groups until the number of samples is completed. The sampling method is a double blocking.

Settings and conduct

This study will be conducted in Kowsar Hospital in Sanandaj city. The aim of this study is to compare the effect of local anesthetic injection site on the quality of intravenous block (bier block) in upper limb. The researcher is aware of the type of intervention but the patients are unaware of grouping, therefore the study is single blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 10 to 70 years, no drug addiction, no history of lidocaine allergy Exclusion Criteria: Drug Addiction, alcohol or painkillers consumption before entering the operating room, allergy to local anesthetics, cardiovascular disease, use of antidepressants, hypertension, seizures

Intervention groups

Intervention group: The angiocath is placed in the proximal part of the forearm. After draining the blood of upper limb, a tourniquet will apply on the arm. 3 mg/kg lidocaine 0.5% is administered through the angiocath and then the angiocath is removed. Control group: The angiocath is placed in the distal part of the forearm. After draining the blood of upper limb, a tourniquet will apply on the arm. 3 mg/kg lidocaine 0.5% is administered through the angiocath and then the angiocath is removed.

Main outcome variables

Sensory hand block and hand motor block measured 5 minutes after the intervention and at the end of surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200126046268N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Kambiz Javavdzadeh Siahkalrudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 6631 1231

Email address

kambiz51js@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-26, 1398/10/05

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of local anesthetic injection site on the quality of intravenous block (bier block) in upper limb

Public title

Comparing the effect of local anesthetic injection site on the quality of intravenous block

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 10 to 70 years No drug addiction No history of lidocaine allergy

Exclusion criteria:

Drug Addiction Alcohol or painkillers consumption before entering the operating room Allergy to local anesthetics, Cardiovascular disease Use of antidepressants Hypertension Sseizures

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

From a package of 70 cards, patients choose one card randomly. The letter A for the control group (Angiocath in the distal) and the letter B for the intervention group (Angiocath in the proximal). There are 35 patients in each group. Patients are then assigned to one of the intervention and control groups. Sampling continues in two groups until the number of samples is completed. The sampling method is a double blocking.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are not aware of grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2019-12-24, 1398/10/03

Ethics committee reference number

IR.MUK.REC.1398.219

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

Fracture of forearm

ICD-10 code

S52.0

ICD-10 code description

Fracture of upper end of ulna

2**Description of health condition studied**

hand laceration

ICD-10 code

s61.9

ICD-10 code description

Open wound of wrist and hand part, part unspecified

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

Hand sensory block

Timepoint

5, 10, 15, 20, 25 and 30 minutes after intervention

Method of measurement

It is measured based on the complete return of sense by clinical examination as touch and stimulation by pin break. Zero- No pain, 1- mild pain, 2- Moderate pain, 3- Severe pain, 4- Unbearable pain

2**Description**

Hand motor block

Timepoint

Five minutes after intervention and at the end of surgery

Method of measurement

It is scored based on the hand movement status: Zero- Unable to move any part of the limb, 1- Able to move fingers, 2- Able to move the limb from the wrist area, 3- Able to move the limb from the elbow area

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The angiocath is placed in the proximal part of the forearm. After draining the blood of upper limb, a tourniquet will apply on the arm. 3 mg/kg lidocaine 0.5% is administered through the angiocath and then the angiocath is removed.

Category

Treatment - Other

2

Description

Control group: The angiocath is placed in the distal part of the forearm. After draining the blood of upper limb, a tourniquet will apply on the arm. 3 mg/kg lidocaine 0.5% is administered through the angiocath and then the angiocath is removed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Kambiz Javadzadeh Siahkalrudi

Street address

Kowsaer Hospital, Boranaldin Hamdi Ave., Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66179-83476

Phone

+98 87 3361 1231

Email

Kambiz51js@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

Pasdaran St., Kurdistan University of Medical Sciences,

Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4653

Email

Maleki43@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Kambiz Javadzadeh Siahkalrudi

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Kowsar Hospital, Boranaldin Hamdi Blv., Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66179-83476

Phone

+98 87 6631 1231

Email

Kambiz51js@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences
Full name of responsible person
Shahpor Shoja
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Kowsar Hospital, Boranaldin Hamdi Blv., Sanandaj,
Iran
City
Sanandaj
Province
Kurdistan
Postal code
66179-83476
Phone
+98 87 3361 1231
Email
shshoja@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Kambiz Javadzadeh Siahkalrudi
Position
Resident of Anesthesiology
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Kowsar Hospital, Boranaldin Hamdi Blv., Sanandaj,
Iran
City
Sanandaj
Province
Kurdistan
Postal code

66179-83476
Phone
+98 87 6631 1231
Email
Kambiz51js@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on the main outcomes of the study can be shared.

When the data will become available and for how long

One year after the publication the data will be available.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Dr. Kambiz Javadzadeh Siahkalrudi, Pasdaran St.,
Kurdistan University of Medical Sciences, Sanandaj, Iran ,
Email: Kambiz51js@gmail.com

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

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email.

Comments