

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative evaluation of lidocaine 0.5% and lidocaine 0.25% with pethidine for intravenous regional anesthesia in upper limb soft tissue surgery

Protocol summary

Study aim

Comparative evaluation of lidocaine 0.5% and lidocaine 0.25% with pethidine for intravenous regional anesthesia in upper limb soft tissue surgery

Design

The present clinical trial had a control group, with parallel groups, one-way blind, randomized, phase 2-3 on 50 patients. Sealedenveloped.com was used for randomization.

Settings and conduct

A person who is unaware of the type of study group is taking medication. In both study groups, single syringes with the same medicinal volume of 40 cc and the same color will be used. Profile of patients classified separately by the only person who has no involvement in the procedure information, not just the Physicians is uncertain. Patients in the first intervention group will receive 3 mg / kg lidocaine 2% in 40 cc syringe for biers block. Patients in the second intervention group will receive combination of 1.5 mg / kg lidocaine 2% and 1.5 mg / kg pethidine for biers block in 40 cc syringe.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 to 60 years old, Patients Candidate for Upper Limb Surgery ASA One and Two. Exclusion Criteria: Heart disease ,High blood pressure and low blood pressure ,Bradycardia, Hyperthyroidism ,Cardiac block, Adrenoceptor agonist and antagonist , Peripheral neuropathy ,Pregnancy , Addiction , Allergy to the drugs used in the study, Coagulation Disorders ,Topical infections ,Patient refusal, Problems and deformities of musculoskeletal of the upper limb.

Intervention groups

Patients in the first intervention group will receive 3 mg / kg lidocaine 2% in 40 cc syringe for biers block. Patients in the second intervention group will receive combination of 1.5 mg / kg lidocaine 2% and 1.5 mg / kg pethidine for biers block in 40 cc syringe.

Main outcome variables

Evaluation of the blocks of sensory nerves within the four main branches of the hand nerve, Evaluation of motor nerve block .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N115**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

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

2021-04-19, 1400/01/30

Expected recruitment end date

2021-06-03, 1400/03/13

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of lidocaine 0.5% and lidocaine 0.25% with pethidine for intravenous regional anesthesia in upper limb soft tissue surgery

Public title
Comparative evaluation of lidocaine 0.5% and lidocaine 0.25% with pethidine for intravenous regional anesthesia in upper limb soft tissue surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 18 to 60 years old, Patients Candidate for Upper Limb Surgery ASA One and Two
Exclusion criteria:
 Heart disease High blood pressure and low blood pressure Bradycardia Hyperthyroidism Cardiac block Using Adrenoceptor agonist and antagonist Peripheral neuropathy Pregnancy Addiction Allergy to the drugs used in the study Coagulation Disorders Topical infections Patient refusal Problems and deformities of musculoskeletal of the upper limb

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
All patients were randomly divided into two groups: A and B. Patients were randomly divided into two groups using Randomization.org site and Random permutations method.

Blinding (investigator's opinion)
Double blinded

Blinding description
A person who is unaware of the type of study group is taking medication. In both study groups, single syringes with the same medicinal volume of 40 cc and the same color will be used. Profile of patients classified separately by the only person who has no involvement in the procedure information, not just the Physicians is uncertain.

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

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.SUMS.MED.REC.1398.574

Health conditions studied

1

Description of health condition studied

upper limb surgeries

ICD-10 code

T79.A12D

ICD-10 code description

Traumatic compartment syndrome of left upper extremity, subsequent encounter

Primary outcomes

1

Description

Evaluation of the blocks of sensory nerves within the four main branches of the hand nerve.

Timepoint

Every 30 seconds

Method of measurement

Pin prick Test

2

Description

Evaluation of motor nerve block

Timepoint

Every 30 seconds

Method of measurement

Assessment of flexion and extension ability of wrists and fingers

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the first intervention group will receive 3 mg / kg lidocaine 2% in 40 cc syringe for biers block.

Category

Prevention

2

Description

Intervention group: Patients in the second intervention group will receive combination of 1.5 mg / kg lidocaine 2% and 1.5 mg / kg pethidine for biers block in 40 cc syringe.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Heidar Safari

Street address

Chamran Hospital, Chamran Boulevard

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7194815644

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chamhosp@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

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

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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

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

Heidar Safari

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Afshin Amini

Position

Anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

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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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Its against our policies.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available