Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of two methods of Intera venous regional anesthesia: Use of one tourniquet versus traditional method in upper limb surgery

Protocol summary

Summary

The aim of the study: Comparison of efficacy of two methods of Intera venous regional anesthesia with use of one tourniquet versus traditional method in distal upper limb orthopedics surgery Study population: Inclusion criteria: Patients' age limit from 50 to 20 years, ASA class I, orthopedic surgery with orthopedic interest has been detected in less than 60 minutes. Exclusion criteria: Obesity, peripheral vascular disease, Raynaud's phenomenon, scleroderma, Epilepsy, sickle cell anemia, Methemoglobin, patients with any history of drug allergies and diseases such as heart disease - smoking, high blood pressure, coagulation disorders, excessive bleeding, Hb less than 10, use Calcium Canal Blockeror Beta blocker, renal failure, drug abuse and patient who did not have necessary cooperation and skin infection in axillary region Sample: 80 Patients Intervention: 5 minutes after lidocaine injection to complete sensory block occurs Vital signs and tourniquet pain patients (based on criteria VAS) at 0, 15, 30, 60 are recorded. In Group D (double tourniquet) each time the patient had complained tourniquet pain distal tourniquet was placed on the numb, inflate and the proximal tourniquet is empty and if the patient still had residual pain, narcotic (fentanyl) is injected. But in Group S (single tourniquet) just from a wider deflation (cm 12) against double tourniquet (a tourniquet cm 6) are used, as soon as the patient's pain narcotic (fentanyl) is injected and every time the patient complained of tourniquet pain, narcotics are injected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041111898N4**

Registration date: **2013-05-07, 1392/02/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Ahmadreza Mirbolouk

Name of organization / entity

Guilin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 2250

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of two methods of Intera venous regional anesthesia: Use of one tourniquet versus traditional method in upper limb surgery

Public title
Comparison of efficacy of two methods of Intera venous regional anesthesia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Patients' age limit from 50 to 20 years, ASA class I, orthopedic surgery with orthopedic interest has been detected in less than 60 minutes. Exclusion criteria: Obesity, peripheral vascular disease, Raynaud's phenomenon, scleroderma, Epilepsy, sickle cell anemia, Methemoglobin, patients with any history of drug allergies and diseases such as heart disease - smoking, high blood pressure, coagulation disorders, excessive bleeding, Hb less than 10, use Calcium Canal Blockeror Beta blocker, renal failure, drug abuse and patient who did not have necessary cooperation and skin infection in axillary region
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University Of Medical Sciences
Street address
Central Building of Guilan University of Medical Sciences, Opposite the Azodi Stadium, Namjoo Stree
City
Rasht
Postal code
Approval date
2013-02-09, 1391/11/21
Ethics committee reference number
1910396407

Health conditions studied

1

Description of health condition studied
Fracture of upper limb
ICD-10 code
T10
ICD-10 code description
Incl.: Broken arm NOS Fracture of arm NOS. The following subdivisions are provided for optional use in a supplementary character position where it is not possible or not desired to use multiple coding to identify fracture and open wound; a fracture not in

Primary outcomes

1

Description
VAS Score
Timepoint
0, 15, 30 & 60 min after complete sensory block occurs
Method of measurement
with VAS score based on patient report

2

Description
Complications
Timepoint
0, 15, 30 & 60 min after complete sensory block occurs
Method of measurement
Based on clinical judgment, with agitation, anxiety, seizures, impaired consciousness, cardiovascular complications

Secondary outcomes

empty

Intervention groups

1

Description
Changing tourniquet and If remain pain narcotic is injected
Category
Other

2

Description
Injection narcotic
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Department, Guilan University of Medical Sciences

Full name of responsible person

Rasoul Tabari (pHD)

Street address

Research and Technology Department, Guilan University of Medical Sciences, opposite of agriculture bank, Gas _ circle

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Technology Department, Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Medical Student

Full name of responsible person

Mohammad Sadeq Mousavi

Position

Research and Technology Department, Guilan University of Medical Sciences

Other areas of specialty/work

Street address

Poursina Hospital, Higher than the Census Bureau, Poursina intersection

City

Rasht

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Ahmadreza Mirbolouk (MD)

Position

Orthopaedic surgeon

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Orthopaedic Research Center,Guilan University of Medical Sciences

Full name of responsible person

Mohammadsadeq Mousavi

Position

Medical Student

Other areas of specialty/work

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Fax

Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty