

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

□ Evaluation Of Mexiletine Effect On BIS Index Change & Hemodynamic Responses To Endotracheal Intubation & During General Anesthesia in upper limbs surgeries

Protocol summary

Summary

By many Researches it has been shown that painful stimulations during laryngoscopy and intubation not only increases Bp,HR of the patients but also BIS index. One of the ways to decrease these changes, is using drugs either as premedications or during anaesthesia induction. one of the drugs of this group is Lidocaine and by some researches its proved that this drug has a great role on decreasing the changes of haemodynamic status and BIS index of the patients. By our research the haemodynamic and BIS index changes are studied after intubation and during general anaesthesia with using Mexiletine Inclusion Criteria: Patients scheduled for upper limb orthopedic surgery under G.A with A.S.A 1,2, aged 20-60 yrs. Exclusion Criteria: Liver disorders, positive history of sensitivity to local anesthetic drugs, bradycardia, pregnant and nursing women, seizure disorders, C.N.S problems and heart blocks. 50 patients (between the ranges of 20-60 yrs) are divided randomly in 2 groups. 2 hours before inducing anaesthesia, Mexiletine (200mg/po) is taken by the case group and Multivitamin by the control group. BP, HR and BIS index of both groups are measured before induction and intubation, 1, 3, 10 minutes after intubation, after incision of the surgery and then every 15 minutes till the end of the operation and finally the results are compared with each others.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109067488N1**
Registration date: **2012-12-28, 1391/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-28, 1391/10/08

Registrant information

Name

Mohammadali Haghbini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

kerman university of medical sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

□ Evaluation Of Mexiletine Effect On BIS Index Change & Hemodynamic Responses To Endotracheal Intubation & During General Anesthesia in upper limbs surgeries

Public title

Effect of Mexiletine on depth of anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion Criteria: Patients scheduled for upper limb orthopedic surgery under G.A with A.S.A 1,2, aged 20-60 yrs. Exclusion Criteria: Liver disorders, positive history of sensitivity to local anesthetic drugs, bradycardia, pregnant and nursing women, seizure disorders, C.N.S problems and heart blocks. Patients in whom more than 15 sec were required for tracheal intubation were excluded from the study

Age
 From **20 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 kerman University of Medical Sciences
Street address
 Jomhoori street
City
 kerman
Postal code
Approval date
 2012-05-19, 1391/02/30
Ethics committee reference number
 91/57/15

2

Ethics committee
Name of ethics committee
 Kerman University of Medical Sciences
Street address
 Jomhoori street
City
 Kerman

Postal code
Approval date
 2012-05-19, 1391/02/30
Ethics committee reference number
 91/57/15

Health conditions studied

1

Description of health condition studied
 B.I.S index, B.P, H.R
ICD-10 code
 S40-S41_S4
ICD-10 code description
 Injuries to upper extremity

Primary outcomes

1

Description
 B.I.S index
Timepoint
 Before and 3 minutes after induction of anesthesia and 1,3.10minutes after intubation, incision of surgery and every 15 minutes till the end of operation.
Method of measurement
 monitoring of depth of anesthesia

2

Description
 Systolic Blood pressure
Timepoint
 Before and 3 minutes after induction of anesthesia and 1,3.10minutes after intubation, incision of surgery and every 15 minutes till the end of operation.
Method of measurement
 mmhg by NIBP Monitoring

3

Description
 Diastolic Blood pressure
Timepoint
 Before and 3 minutes after induction of anesthesia and 1,3.10minutes after intubation, incision of surgery and every 15 minutes till the end of operation.
Method of measurement
 mmhg by NIBP monitoring

4

Description
 Heart Rate
Timepoint
 Before and 3 minutes after induction of anesthesia and 1,3.10minutes after intubation, incision of surgery and every 15 minutes till the end of operation.
Method of measurement
 Heart Rate by electronic monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Case group: Mexiletine Cap 200 mg , 2hours before operation

Category

Treatment - Drugs

2

Description

control group :Multivitamin Cap ,2hours before operation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

[Orthopedic Operating Room of Bahonar Hospital

Full name of responsible person

Dr Mohammad Ali Haghbin

Street address

General Operating room Of Shafa Hospital

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Faranak khezri

Street address

Jomhoori street

City

kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical sciences

Full name of responsible person

Dr Mohammad Ali Haghbin

Position

Assistant Professor of Anesthesia

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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