

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 Haghbin

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1211 5814

###### Email address

m.a.haghbin@gmail.com

##### 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 neursing 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.Sindex,B.P,H.R

#### **ICD-10 code**

S40-S41\_S4

#### **ICD-10 code description**

Injuries to upper extrimity

## **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 pressur

#### **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 pressur

#### **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**

mmgh by NIBP manitoring

### 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

##### Street address

General Operating Room Of Shafa Hospital

##### City

kerman

##### Postal code

##### Phone

+98 34 1211 5780

##### Fax

##### Email

m.a.haghbin@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Ali Haghbin

##### Position

Assisstan Professor of Anesthesia

##### Other areas of specialty/work

##### Street address

General operating room of Shafa Hospital

##### City

kerman

##### Postal code

##### Phone

+98 341

##### Fax

##### Email

m.a.haghbin@gmail.com

##### Web page address

## Person responsible for updating data

#### 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

##### Street address

Shafa Hospital

**City**

Kerman

**Postal code****Phone**

00

**Fax****Email**

m.a.haghbin@gmail.com

**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*