

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Analgesic effect of different doses of granisetron with lidocaine for intravenous regional anesthesia

Protocol summary

Summary

The purpose of the study is to compare different doses effect of granisetron with lidocaine for intravenous regional anesthesia. Plan: randomized, double blind, without placebo, phase III clinical trial. .Inclusion criteria: age of 20 to 50, ASA I or II Exclusion criteria: Drug allergy history, Pregnancy, contraindication of intravenous regional anesthesia like sickle cell anemia. Target sample size: 210. Interventions: control group will take 3 mg/kg lidocaine 0.5 %diluted to saline 0.9% will infuse over 90 seconds. Second group will take 3mg/kg lidocaine 0.5% with 1 mg granisetron diluted to saline 0.9% will infuse over 90 seconds. Third group will take 3 mg/kg lidocaine 0.5% with 2 mg granisetron diluted to saline 0.9% will infuse over 90 seconds. Primary outcome: reduction in tourniquet pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091214056N4**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 9680

Email address

he_modir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2014-05-06, 1393/02/16

Expected recruitment end date

2015-07-07, 1394/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effect of different doses of granisetron with lidocaine for intravenous regional anesthesia

Public title

Analgesic effect of different doses of granisetron with lidocaine for intravenous regional anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 to 50 years old; ASA I or II. Exclusion criteria: history of drug allergy; pregnancy; contraindication of intravenous regional anesthesia like sickle cell anemia; use of opiate and analgesic drugs; use of Apomorphine.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

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

Ethical committee of Arak University of Medical Sciences

Street address

Arak University Of Medical Science, Basij Square

City

Arak

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

7- 163- 93

Health conditions studied

1

Description of health condition studied

Regional anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Tourniquet pain

Timepoint

0, 15, 30 and 45 minute after injection

Method of measurement

VAS

Secondary outcomes

1

Description

Reduction of pain

Timepoint

Every 30 minutes until 2 hours after removing tourniquet

Method of measurement

VAS

2

Description

Vital signs

Timepoint

After removing tourniquet

Method of measurement

Physical examination

3

Description

O2 saturation

Timepoint

After removing tourniquet

Method of measurement

Pulse oxymeter

4

Description

Need to Fentanyl

Timepoint

0, 15, 30 and 45 min after injection

Method of measurement

Drug dose that is used

Intervention groups

1

Description

Intervention group will take 3 mg/kg lidocaine 0.5% with 1 mg granisetron diluted to 40 cc saline 0.9% will infuse over 90 seconds.

Category

Treatment - Drugs

2

Description

Control group will take 3 mg/kg lidocaine 0.5% diluted to 40 cc saline 0.9% will infuse over 90 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-e-Asr hospital
Full name of responsible person
Hesameddin Modir
Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak.
City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Dr Saeed Changizi Ashtiani
Street address
Arak University Of Medical Science, Basij Square
City
Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice chancellor for research

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
Vali-e-Asr hospital
Full name of responsible person
Hesameddin Modir
Position
Anesthesiologist/ Assistant Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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