Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak.
City
Arak
Postal code
Phone
+98 86 3223 1104
Fax
Email
he_modir@arakmu.ac.ir
Web page address

Person responsible for scientific 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
Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak.
City
Arak
Postal code
Phone
+98 86 3223 1104
Fax
Email
he_modir@arakmu.ac.ir
Web page address

Person responsible for updating data

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
Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak.
City
Arak
Postal code
Phone
+98 86 3223 1104
Fax
Email
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