Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparisson effect of pretreatment with ondansetron, lidocaine and paracetamol drugs on pain reduction due to interavenous injectionof Propofol

Protocol summary

Summary

The main objective of this study is comparison effect of pretreatment with Ondansetron, lidocaine and Paracetamol drugs on pain reduction due to interavenous injection of Propofol and Determination the best drug available to reduce injection pain of Propofol. The study is double-blind clinical trial.The target population will be patients who admitted to Besat hospital for elective general surgery. The sample size will be 164 patients in four groups, Each group 41 patients including the control group, ondansetron group, lidocaine group and paracetamol group. The premedication status in all groups before surgery will be quite similar and no additional medicines receive. patients in all study groups receive equal volume of medications by IV access number 20 on the largest vessel on the hand and after two minutes, a quarter of the total dose of Propofol 1% will injected during 20 seconds and During this period purpofol injection pain measuring by VRS(four-point Verbal Rating Scale) which contains no pain = 0, mild= 1, moderate= 2, and severe=3. The site of drugs injection will be evaluated in term of pain, edema, allergic reactions and other side effects by the investigator over 2 hours after injection and record in the questionnaire

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015112325202N1**
Registration date: **2016-01-31, 1394/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-31, 1394/11/11

Registrant information

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Name of organization / entity
Hamedan University of Medical Of Science
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisson effect of pretreatment with ondansetron, lidocaine and paracetamol drugs on pain reduction due to interavenous injectionof Propofol

Public title

Comparison of the three types of drugs to reduce propofol pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: " age 18 to 65 years" "patients with ASA class 1 and 2" " patients undergoing elective surgery" Exclusion criteria:" (1) patients with ASA class of 3 or higher 2. Patients with a history of HTN and DM 3. Patients with a history of narcotic or psychotropic abuse or NSAID 4. The patient who are contraindicate for propofol, ondansetron, paracetamol and lidocaine drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

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

Ethics committee of Hamadan Univercity of Medical Science

Street address

shahid fahmideh avenue

City

Hamadan

Postal code

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

Umsha.REC.1394.81 IR

Health conditions studied

1

Description of health condition studied

Acut pain after propofol injection

ICD-10 code

R52.0A

ICD-10 code description

pain, Vomiting, nausia

Primary outcomes

1

Description

Reduce the pain of Propofol injection

Timepoint

Along with propofol infusion in 20 seconds

Method of measurement

four-point verbal rating scale = VRS) which contains no pain = 0 , mild= 1 , moderate= 2 and severe =score 3 (by tearing or rejection injected organs or patient complain of pain or frown)

Secondary outcomes

1

Description

Check of pain and swelling and allergic reactions of drugs within 2 hours after injection were recorded in questionnair

Timepoint

within 2 hours after injection of drugs

Method of measurement

Observation and question

Intervention groups

1

Description

Intervention 1: Paracetamol: Closing pressure cuff on the arm on the same side and blowing tourniquet pressure to 70 mm Hg, partial occlusion of the venous system has been established and this drug will be injected within 10 seconds, after 2 minutes cuff pressure discharge and a quarter of total dose Propofol 1% (2.5 mg kg) of Austria in order freseniuskabi company darman yab daro within 20 seconds will inject from the desired vein.

Category

Treatment - Drugs

2

Description

Intervention 2:ondancetronl: Closing pressure cuff on the arm on the same side and blowing tourniquet pressure to 70 mm Hg, partial occlusion of the venous system has been established and this drug will be injected within 10 seconds, after 2 minutes cuff pressure discharge and a quarter of total dose Propofol 1% (2.5 mg kg) of Austria in order freseniuskabi company darman yab daro within 20 seconds will inject from the desired vein

Category

Treatment - Drugs

3

Description
Intervention 3: lidocain: Closing pressure cuff on the arm on the same side and blowing tourniquet pressure to 70 mm Hg, partial occlusion of the venous system has been established and this drug will be injected within 10 seconds, after 2 minutes cuff pressure discharge and a quarter of total dose Propofol 1% (2.5 mg kg) of Austria in order freseniuskabi company darman yab daro within 20 seconds will inject from the desired vein
Category
Treatment - Drugs

4

Description
Control group: distilled water all steps will be similar to the intervention group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mohammad zolhavarieh
Street address
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
parisa shirzad
Full name of responsible person
parisa shirzad
Street address
Hamadan University Of Medical Science
City
Hamadan
Grant name
0
Grant code / Reference number
0
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
parisa shirzad
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
Hamadan University Of Medical Science
Full name of responsible person
Parisa Shirzad
Position
Student of anesthesia
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Web page address

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Person responsible for updating data

Contact
Name of organization / entity
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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