Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of the effect of intravenous analgesia by paracetamol compared to fentanyl in patients undergo coronary heart bypass surgery

Protocol summary

Summary

Objective: Clinical trial of the effect of intravenous analgesia by paracetamol compared to fentanyl in patients undergo coronary heart bypass surgery. Design of the study: randomization using random permuted blocks, convenience sampling, double-blind, single-center, phase II trial. Study population: all patients with stage 5 of renal failure. Main inclusion criteria: pre-operation ejection fraction above 30%; class one to three of ASA; no simultaneous heart valves involvement; no need of intra-aort pump usage during the operation. Main exclusion criteria: positive history of sensitivity to study drugs; uncontrolled systemic disease such as diabetes; addiction to alcohol and drugs; positive history of psychologic disease and depression; asthma and other hypersensitivity reactions; fracture of sternum and ribs intraoperation; pre-operative liver enzymes rising higher than two folds; other chest pain causes other than coronary arteries; presence of neurologic signs and symptoms; any type of consciousness impairment pre-operation. Sample size: 160. Interventions: First group: Bolus intravenous infusion of 50 microgram fentanyl followed by pump infusion of 10 microgram per cc in speed of 4 cc in hour; second group: bolus intravenous infusion of 15 microgram per kilogram of paracetamol followed by pump infusion of 25 micrograms per cc in speed of 4 cc in hour. Intervention time: after the operation and before being transferred to ICU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121131351N1**
Registration date: **2017-01-27, 1395/11/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name
Yalda Moeini
Name of organization / entity
Zahedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2015-10-02, 1394/07/10

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of intravenous analgesia by paracetamol compared to fentanyl in patients undergo coronary heart bypass surgery

Public title

Comparison the effect of intravenous analgesia by paracetamol versus fentanyl in patients undergo coronary heart surgery

Purpose
Supportive
Inclusion/Exclusion criteria
Main inclusion criteria: pre-operation ejection fraction above 30%; class one to three of ASA; no simultaneous heart valves involvement; no need of intra-aort pump usage during the operation. Main exclusion criteria: positive history of sensitivity to study drugs; uncontrolled systemic disease such as diabetes; addiction to alcohol and drugs; positive history of psychologic disease and depression; asthma and other hypersensitivity reactions; fracture of sternum and ribs intraoperation; pre-operative liver enzymes rising higher than two folds; other chest pain causes other than coronary arteries; presence of neurologic signs and symptoms; any type of consciousness impairment pre-operation.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **160**
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
Ethics Committee of Zahedan University of Medical Sciences
Street address
Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan
City
Zahedan
Postal code
Approval date
2015-09-20, 1394/06/29
Ethics committee reference number
IR.ZAUMS.REC.1394.238

Health conditions studied

1

Description of health condition studied
Coronary artery bypass
ICD-10 code
I25, I25.0
ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
Postoperation pain
Timepoint
Two houres, four houres, eight houres, 12 houres and 24 houres after surgery
Method of measurement
VAS Criteria

2

Description
Mean arterial pressure
Timepoint
Up to 24 hours after surgery in intervals of every 4 hours
Method of measurement
Millimeter of mercury

3

Description
Heart rate
Timepoint
Up to 24 hours after surgery in intervals of every 4 hours
Method of measurement
Beats in minute

Secondary outcomes

empty

Intervention groups

1

Description
First group: Bolus intravenous infusion of 50 microgram fentanyl followed by pump infusion of 10 microgram per cc in speed of 4 cc in hour
Category
Treatment - Drugs

2

Description
Second group: Bolus intravenous infusion of 15 microgram per kilogram of paracetamol followed by pump infusion of 25 microgram per cc in speed of 4 cc in

hour

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Yalda Moeini

Street address

Operation room, Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Yalda Moeini

Position

Anesthesiology Residence

Other areas of specialty/work

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Position

Cardiac Anesthesia Fellowship

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Fax
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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