

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5799

Email address

yaldamoini@zaums.ac.ir

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 heures, four heures, eight heures, 12 heures and 24 heures 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

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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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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