

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The comparison of opioid consumption in general anesthesia and general anesthesia plus spinal anesthesia in opium addicted patient under coronary artery bypass graft surgery

Protocol summary

Summary

This study is a clinical trial on 66 patients with average age 40_75 years old, whom had history of opioid consumption that were candidated for CABG. exclusion criteria were non sinusoidal heart rythm, operation time more than 2hours, emergency operation and affected to coagulopathy. then the patients devided to 2 groups with general anesthesia only and general plus spinal anesthesia. the second group received 20 mg bupivacain0.5% plus 0.6 micro geram per kilogeram morphin that was injected interatechally. then both groups received general anesthesia in the same way, heart rate and blood pressure of the patients were controlled at the arrival time, sternotomy, intubation, pump attachment, pump dettachment and the end of operation. the mean arterial blood pressure was controlled at the range of 60_90 mm hg and heart rate at the range of 60_100 per min by some medications including beta blockers, vasodilators, vasoactive agents, opoids, sedative and cardiac stimulators that was registered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091910881N1**
Registration date: **2013-01-16, 1391/10/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-16, 1391/10/27

Registrant information

Name

Arash Gorjizadeh

Name of organization / entity

University

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor research- Ahvaz Jondishapur University
Medical Science

Expected recruitment start date

2011-06-24, 1390/04/03

Expected recruitment end date

2012-04-22, 1391/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of opioid consumption in general anesthesia and general anesthesia plus spinal anesthesia in opium addicted patient under coronary artery bypass graft surgery

Public title

Opioid consumption in cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 40_75 years old age patients were candidated for CABG ; (ASA) claass 2_3 ; History of

opium abuse at least 1 time at a week for a 6 months period of time
Exclusive criteria: Not satisfaction; Additive procedure to CABG; Lumbar disk; Infection of spinal injection site; Coagulopathy; Non sinusoidal heart rhythm; Pump time more than 2 hours; Emergency surgery; Cr clearance less than 50 ml/min

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Ahvaz Jondishapur University
Medical Science

Street address

Golestan blv, Ahvaz Jondishapur University Medical
Science

City

Ahvaz

Postal code

Approval date

2011-10-12, 1390/07/20

Ethics committee reference number

ETH 470

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R.52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Opiod consumption

Timepoint

During and after surgery

Method of measurement

Opiod consumption base on mg and micro gram

2

Description

Pain

Timepoint

From the begining

Method of measurement

Visual analoge scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Arrival time, Esternotomy, Intubation, Pump attachemen,
pump dettachment and the end of operation

Method of measurement

ml/hg

2

Description

Heart rate

Timepoint

Arrival time, Esternotomy, Intubation, Pump attachemen,
pump dettachment and the end of operation

Method of measurement

Beat per minute

Intervention groups

1

Description

General anesthesia in control group

Category

Treatment - Drugs

2

Description

In intervention group, bupivacaine 20mg single dose and
morphin 0.6 mg intratechal single dose. after that
general anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr.Seyed Kamalaldin Tabatabaie

Street address

Golstan blv

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Dr.mostafa fegghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Science

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

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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