Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

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 sinosoidal 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 attachement, 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

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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 surgury

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 mounths period of time Exclusive criteria: Not satisfaction; Additive procedure to CABG; Lumbar disk; Infection of spinal injection site; Coagulopathy; Non sinosoidal heart rythm; Pump time more than 2hours ; Emergency surgury ; 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
Visuai analoge scale

Secondary outcomes

1

Description
Blood pressure

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

Method of measurement
ml/hg

2

Description
Heart rate

Timepoint
Arrival time, Esternotomy, Intubation, Pump attachemen, pump dettachement 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 Tabatabaii
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
Full name of responsible person
Dr.mostafa feghhi
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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

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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