Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Impact of patient - controlled analgesia on patient's satisfaction after coronary artery bypass surgery in Shahid Rajaei Heart center in 2011.

Protocol summary

Summary

Main outcome: To determine the impact of patient - controlled analgesia on patient's satisfaction after coronary artery bypass surgery Objectives: - to compare patient's satisfaction with patient controlled analgesia method in two groups - To determine the correlation between demographic data with patient's satisfaction of pain control - to determine nurses opinions about patient controlled analgesia method - to determine pain severity in two groups - to determine level of sedation in two groups After approving the design and confirming the Questionnaire with the ethical considerations, we will take the permission of Research Deputy of Nursing Faculty. After coordination with hospital And ICU, the researcher will present the study goals; take the patients consents and their willing to participation in study. Then they will receive explanations about pain control satisfaction questionnaire a day before surgery. Participants including major eligibility criteria: patients with coronary artery bypass surgery Design: In a randomized control trail, with convenience sampling, patients after Coronary Artery Bypass Surgery in ICU of Shahid Rajaie Heart Center of Tehran, will randomly allocated to two groups. Intervention: The interventional group, to be trained using Patient Control Analgesia (PCA). (In this method the physician determines the type and parameters of analgesia doses and patient just have control on injection pump and when he needs to analgesia, pushes the pump so the set adjusted based on physician order and patient cannot receive more than ordered parameters). In control group the pain will control by the nurse (Nurse Control Analgesia) as usual. Sample size will determine after pilot study. Setting and conduct: During two days the satisfaction of patients with the pain control will be asked by a blinded nurse, and she will fill in the Questionnaire. At the end, the satisfaction with the pain control in two groups will compare statistically by SPSS. main outcome measures (variables):satisfaction of patients dependent variable and pain control method as independent variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103195665N2**
Registration date: **2011-07-20, 1390/04/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-20, 1390/04/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz Medical Science University, Vice chancellor for research , Nursing and Midwifery Faculty

Expected recruitment start date

2011-08-20, 1390/05/29

Expected recruitment end date

2012-01-16, 1390/10/26

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Impact of patient - controlled analgesia on patient's satisfaction after coronary artery bypass surgery in Shahid Rajaei Heart center in 2011.

Public title
Impact of patient - controlled analgesia on patient's satisfaction after cardiac surgery in Shahid Rajaei Heart center in 2011.
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: age 30-60 years old; admission in cardiac surgery ICU for bypass surgery; consent for participation in research Exclusion criteria: to have addiction; sensitivity for Morphine; not to be able for working with patient control anesthesia; renal diseases with creatine more than2; liver disease; to have re surgery for bleeding; psychological disease; unstable hemodynamic status with blood presser less than 90 mmHg, and receiving inotrope medications; low consciousness; ejection fraction less than %30;entrance to operating room by emergency; intubation more than 6 hours.
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size:
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
Tabriz Medical Science University, Vice chancellor for research, Ethics committee
Street address
Vice chancellor for research, Amoozesh Building, Tabriz Medical Science University, Daneshgah Ave, Tabriz
City
Tabriz
Postal code
Approval date
2011-04-25, 1390/02/05
Ethics committee reference number
1160/4/5

Health conditions studied

1

Description of health condition studied
pain control after heart surgery
ICD-10 code
197.8
ICD-10 code description
Other post procedural disorders of circulatory system, not elsewhere classified

Primary outcomes

1

Description
patient satisfaction of pain control
Timepoint
every 12 hours after heart surgery until 2 days after surgery
Method of measurement
Pain Treatment Satisfaction Scale

Secondary outcomes

1

Description
Nurses opinions about pain control method
Timepoint
every 12 hours after heart surgery until 2 days postsurgery
Method of measurement
by 6 questions about nurses opinions

2

Description
Pain Severity
Timepoint
Every 4 hours for 2 days after surgery
Method of measurement
Visual Analog Scale

3

Description
Sedation level

Timepoint
Every 4 hours for 2 days after surgery
Method of measurement
Sedation Scale

Intervention groups

1

Description
The interventional group, to be trained using Patient Control Analgesia (PCA=Patient Control Analgesia pump).In this method during two days post surgery, the physician determines the type and parameters of analgesia doses and the patient receives the base doses of analgesia by intravenous infusion, and he just have control on injection pump and when he needs to analgesia, pushes the PCA pump so the set adjusted based on physician order and patient demand, so he cannot receive more than ordered parameters). So he can take analgesia before worsen his pain and when he needs more doses of analgesia.
Category
Treatment - Devices

2

Description
In control group the pain will control by the nurse (Nurse Control Analgesia) as usual and routine of unit, based on physician orders, during two days postoperatively. During two days the satisfaction of patients in two groups with the pain control will be completed by a blinded nurse, and she will fill in the Pain Control Satisfaction Questionnaire. At the end, the satisfaction with the pain control in two groups and pain severity scale will compare statistically by SPSS.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Shahid Rajaie Heart Center
Full name of responsible person
Atoosa Hosseinzadeh
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz Medical Science University, Vice chancellor for research, Dr. Mohamreza Rashidi
Full name of responsible person
Soheila Bani,
Street address
5138947-977, Nursing and Midwifery Faculty, Shriati Jnoobi Ave.Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz Medical Science University, Vice chancellor for research, Dr. Mohamreza Rashidi
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