

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

Sima Lakdizaji

Name of organization / entity

Tabriz University of Medical Sciences, Nursing and Midwifery Faculty

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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 than 2; 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.

AgeFrom **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**

Tabriz Medical Science University

Full name of responsible person

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Position

Ms. student in Medical Surgical Nursing, Operating Room Nurse

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Lecturer

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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

Person responsible for updating data

Contact

Name of organization / entity

Tabriz Medical Science University, Vice chancellor for
research

Full name of responsible person

Sima Lakdizaji

Position

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Other areas of specialty/work

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