Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ice bag application on pain associated with sutures removal from incision in leg vein harvest in patients undergoing cardiac surgery(CABG) in Imam Reza hospital at 1392.

Protocol summary

Summary

This randomized controlled clinical trial to evaluate the effect of ice bag application on pain associated with sutures removal from incision in leg vein harvest, on 90 patients undergoing open heart surgery at Imam Reza (AS) in Mashhad at 1392. Inclusion criteria: Undergoing open heart surgery and harvest vein from leg; Age 30 to 70; Ability to reading and writing; At least 5 days from the last leg incision sutures. Exclusion criteria: Use powerful hypnotics or analgesics drugs; Presence of swelling, redness, tenderness at surgical site; Reluctance to continue participating in the exercises. After obtaining permission from the Research Ethics Committee of Sabzevar University of Medical Sciences and informed consent of patients entering the study, patients will randomly allocate to three groups, 30 patients in experimental group 1, 30 in experimental group 2 and 30 in control group. For all three groups, basical pain will assessment according to Visual Analog Scale (VAS) and criteria of quality McGill pain questionnaire. In experimental group 1, ice bag will placed in the surgical site for 10 min and maximum 2 min after removal of the ice, the stitches will remove, then reassess pain was noted on the instrument. This intervention will performe for 20 min in group 2. The control group will not receive any intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071018221N1**
Registration date: **2014-07-10, 1393/04/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-10, 1393/04/19

Registrant information

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Recruitment status

Recruitment complete

Funding source
Sabzevar University of Medical Sciences

Expected recruitment start date

2014-01-05, 1392/10/15

Expected recruitment end date

2014-03-19, 1392/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ice bag application on pain associated with sutures removal from incision in leg vein harvest in patients undergoing cardiac surgery(CABG) in Imam Reza hospital at 1392.

Public title

Application of ice bag to reduce pain caused by sutures removal from leg vein harvest site.

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Consent for participation in the study; Age 30 to 70; Ability to speake Farsi; Ability to reading and writing; Consciousness should be sufficient to determine the severity of pain; Undergoing Heart surgery (coronary artery bypass); At least 5 days from the last leg incision sutures; Be at least 20 cm long incision; Not any psychiatric disorder; Ability to communicate verbally; Not use sedative and analgesics drugs; The patient has no addiction; The patient has no hearing and vision impairments; Patients without neuromuscular diseases such as Burgers, Raynaud and etc; Physician (cardiac surgeon) agrees with participate the patient. Exclusion criteria: Use powerful hypnotics or analgesics drugs; Presence of comorbid disease that affects the patient's pain assessment (delirium, dementia or severe depression, severe impairment of vision and hearing, diabetic neuropathy); Reluctance to continue participating in the exercises; Over the past 15 days of surgery; The patient is allergic to cold; Presence of Swelling, redness or tenderness at surgical site.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sabzevar University of Medical Scinces
Street address
School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar
City
Sabzevar
Postal code

Approval date
2014-01-30, 1392/11/10
Ethics committee reference number
medsab.rec.92.23

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52
ICD-10 code description
Pain, not elsewhere classified

2

Description of health condition studied
Pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain Quality
Timepoint
Before suture removal from leg and 2 minutes after suture removal
Method of measurement
Modify Short Form McGill Pain Questionnaire

2

Description
Pain Intensity
Timepoint
Before suture removal from leg and 2 minutes after suture removal
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
This clinical trial consists of three groups. The patients are divided to three groups randomly assigned; Group 1: Ice bag (bag designed and built by the researcher) apply to the surgical site (on foot vein harvest), for 10 minutes. Time between apply ice bag and sutures removal is 2 minutes.

Category
Other

2

Description
Group 2: Ice bag apply on surgical site for 20 minutes. Time between apply ice bag and sutures removal is 2 minutes.
Category
Other

3

Description
Group 3: After evaluating pain, without any interference, the sutures will remove and then pain evaluate again.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Center of education, research and treatment of Imam Reza
Full name of responsible person
Mostafa Rad, BSN, MSN, Ph.D candidate of Nursing. Faculty Member of Sabzevar University of Medical S
Street address
Shariati square - mashhad - Khorasan Razavi
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Moosa Reza Tadayonfar
Street address
School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
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Person responsible for updating data

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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