

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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, basal 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

Name

Amir Namayandeh Jourabchi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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 speak 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 Sciences

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.
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Shariati square - mashhad - Khorasan Razavi

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Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Moosa Reza Tadayonfar

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School of Nursing and Midwifery; Next to the Police
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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

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****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Amir Namayandeh Jourabchi

Position

Master Student Critical Care Nursing

Other areas of specialty/work**Street address**

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

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Web page address**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