

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of intraperitoneal irrigation with sodium bicarbonate versus normal saline on post-operative pain in patients who are candidate for elective laparotomy: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: to assess the effect of intraperitoneal irrigation with sodium bicarbonate versus normal saline on post-operative pain in patients who are candidate for elective laparotomy. Design: double blind randomized clinical trial. Setting and conduct: the eligible patients who are candidate for elective laparotomy and will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: age 18 to 65 years old; candidate for elective laparotomy. Exclusion criteria: loss of consciousness; heart failure; hemodynamic disorder; renal and hepatic and lung diseases; electrolyte imbalance. Intervention group: intraperitoneal irrigation with sodium bicarbonate plus normal saline for 2 to 5 minutes during surgery. Control group: intraperitoneal irrigation with normal saline for 2 to 5 minutes during surgery. Primary outcome: pain at surgery site 12 and 24 hours post-operation using VAS. Randomization: patients will be randomly assigned to intervention and control groups through drawing lot. Blinding: patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612089014N138**
Registration date: **2016-12-09, 1395/09/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2017-05-05, 1396/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intraperitoneal irrigation with sodium bicarbonate versus normal saline on post-operative pain in patients who are candidate for elective laparotomy: a double blind randomized clinical trial

Public title

Effect of intraperitoneal irrigation with sodium bicarbonate versus normal saline on post-operative pain in patients who are candidate for elective laparotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 65 years old; candidate for elective laparotomy. Exclusion criteria: loss of consciousness; heart failure; hemodynamic disorder; renal and hepatic and lung diseases; electrolyte imbalance.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: patients will be randomly assigned to intervention and control groups through drawing lot. Blinding: patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-06-25, 1395/04/05

Ethics committee reference number

IR.UMSHA.REC.1395.190

Health conditions studied

1

Description of health condition studied

laparotomy

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

pain at surgery site

Timepoint

12 and 24 hours post-operation

Method of measurement

using VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intraperitoneal irrigation with sodium bicarbonate plus normal saline for 2 to 5 minutes during surgery.

Category

Treatment - Drugs

2

Description

Control group: Intraperitoneal irrigation with normal saline for 2 to 5 minutes during surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Roohollah Hoseini

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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**

Besat Hospital

Full name of responsible person

Dr Roohollah Hoseini

Position

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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