Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

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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
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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 Fahmideh Ave
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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

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Person responsible for updating data

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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