

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Impact of subcutaneous injection of 0.5% bupivacaine into skin incision on hemodynamic changes during operation in lower abdominal surgeries.

Protocol summary

Summary

Objectives We aimed to determine the impact of subcutaneous injection of 0.5% bupivacaine into the surgical incision on hemodynamic changes during operation in the lower abdominal surgeries. **Design** In a randomized, case-control clinical trial, phase 3, forty-four patients who were candidate for lower abdominal surgery at sensory level below the umbilicus (anesthesia at T10 level) and referred for surgery to Kowsar hospital enrolled in study. **Setting and conduct** Participating patients were randomly assigned to the intervention or control groups by randomization blocks if they fulfilled inclusion criteria, then interventions were done. **Participants** including major eligibility criteria Patients in class I and II based on American Surgery Association (ASA) classification who candidate for lower abdominal surgery at sensory level below the umbilicus (anesthesia at T10 level) including inguinal hernia, varicoceles and appendectomy, enrolled in study. **All patients** with underlying conditions including heart disease, thyroid disorders, uncontrolled diabetes and age more than 65 years excluded from study. **Intervention** In the case group, bupivacaine was subcutaneously injected into the surgical incision and surgery performed under general anesthesia. In the control group normal saline was subcutaneously injected into the surgical incision as placebo and surgery was done under general anesthesia. **Main outcome measures** Mean arterial blood pressure and heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061024625N3**

Registration date: **2016-11-04, 1395/08/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-04, 1395/08/14

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-07-19, 1395/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of subcutaneous injection of 0.5% bupivacaine into skin incision on hemodynamic changes during operation in lower abdominal surgeries.

Public title

Impact of subcutaneous injection of 0.5% bupivacaine into skin incision on hemodynamic changes during operation.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients in class I and II based on American Surgery Association classification candidate for lower abdominal surgery at sensory level below the umbilicus (anesthesia at T10 level). Exclusion criteria: Underlying heart disease; thyroid disorders; uncontrolled diabetes; age more than 65 years; receiving of calcium channel blockers and beta adrenergic medications; sensitivity to local anesthetics.

Age

To 65 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 44

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization was done by randomized blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Amir Kabir Bridge, Basidje Boulevard

City

Semnan

Postal code

3519747167

Approval date

2015-10-06, 1394/07/14

Ethics committee reference number

IR.SEMUMS.REC.1394.90

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

2

Description of health condition studied

Acute appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

3

Description of health condition studied

Varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

Primary outcomes

1

Description

Atrial blood pressure

Timepoint

During surgery

Method of measurement

Monitoring

Secondary outcomes

1

Description

Heart Rate

Timepoint

During surgery

Method of measurement

Monitoring

Intervention groups

1

Description

In the first group (intervention), bupivacaine 0.5% , 5 mg/kg was subcutaneously injected at the incision site and surgery performed under general anesthesia.

Category

Treatment - Drugs

2

Description

In the second group (control) surgery was done under general anesthesia after subcutaneous injection of normal saline at similar volume in the incision site as placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital, Educational, research and therapeutic center

Full name of responsible person

Parinaz Mirzaei

Street address

Amin Avenue, Basidje Boulevard

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asgari

Street address

Basidje Boulevard

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Semnan

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 of Semnan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Babak Husseinazadeh

Position

Anesthesiologist/ Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Mehrdad Zahmatkesh

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Research Expert

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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

