

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A clinical trial to compare the effectiveness of normal saline with diclofenac suppository and bupivacaine on pain relief following laparoscopic herniorrhaphy surgery

Protocol summary

Study aim

A clinical trial to compare the effectiveness of normal saline with diclofenac suppository and bupivacaine on pain relief following laparoscopic herniorrhaphy surgery

Design

Forty patients who were candidates for laparoscopic herniorrhaphy, clinical trial with a control group, community-based and pragmatic, parallel groups, double-blind, randomized using table of random numbers

Settings and conduct

Patients candidate for laparoscopic herniorrhaphy at the Rasoul Akram Hospital, Tehran, were chosen. In this double-blind study, the participants and responsible for data collection are blinded to the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients with ASA class one or two, who are candidate for laparoscopic herniorrhaphy.
Exclusion criteria: Allergy to the drugs studied; history of hypertension; history of uncontrolled diabetes; history of cardiovascular diseases; history of renal failure, history of cirrhosis; history of smoking or drug abuse; pregnant women.

Intervention groups

The control group are receiving 500 cc normal saline after surgery. The intervention group one are receiving 50 mg diclofenac suppository per 8 hours after surgery. The intervention group two are receiving 0.25% bupivacaine dissolved in 100 ml of physiologic serum after surgery.

Main outcome variables

Evaluation and comparison of pain relief based on the visual analog scale (VAS) 3, 8, 12, 16, 20 and 24 hours after the intervention between three studies groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039782N2**

Registration date: **2018-10-14, 1397/07/22**

Registration timing: **prospective**

Last update: **2018-10-14, 1397/07/22**

Update count: **0**

Registration date

2018-10-14, 1397/07/22

Registrant information

Name

Behnood Farazmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8842 9230

Email address

farazmand.b@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of normal

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-03-08. 1396/12/17

IR.UIMS.FMD.BEC.1396.9311245006

IR.IUMS.FMD.REC 1396.9311245006

Age

1

Description of health condition studied

laparoscopic herniorrhaphy

ICD-10 code

K46

ICD-10 code description

- Unspecified abdominal hernia

Primary outcomes

1

Description

pain relief

Timepoint

3, 8, 12, 16, 20 and 24 hours after the intervention

Method of measurement

based on the visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients are receiving 500 cc normal saline after surgery.

Category

Treatment - Drugs

2

Description

Intervention group: Patients are receiving 50 mg diclofenac suppository per 8 hours after surgery.

Category

Treatment - Drugs

1

Name of ethics committee

3

Description

Intervention group: Patients are receiving 0.25% bupivacaine dissolved in 100 ml of physiologic serum after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Behnood Farazmand

Street address

Rasoul Akram Hospital, Niyayesh Street, Sattarkhan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakoti

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Phone

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PR@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behnood Farazmand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results.

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Behnood Farazmand provides the analysis code to the applicants via email: behnoood@gmail.com

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments