

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of comparison of into wound Marcain with Naproxen suppository analgesic effects in patients with inguinal hernia operation in Shahid Modarres and Imam Hossein hospitals

Protocol summary

Summary

The aim of this study is to comparison between analgesic effects of Marcain injection in wound with Naproxen suppositories in surgery of inguinal hernias. In this not - blinded randomized design, patients were divided into two groups, cases (injection Marcain into wound) ,and controls (Naproxen suppository). After operation of inguinal hernia which was done by Lichtain Eshtain method, the pain was measured by visual analogue scale (VAS),1 and 6 hours and after day of operation. Then statistical comparison was done after the data of two groups were gathered. The sample size were 198 patients that were divided to two groups: 100 patients (Marcain injection) and 98 patients (Naproxen suppository) . Inclusion criteria: All of the patients who scheduled for surgery, inguinal hernia, giving the consent form of participating in the research and had not clinical problems of anesthesia. Exclusion criteria: no consent form to participate in the research, clinical contraindication for anesthesia,clinical problems such as EF <20%, previous history of taking non-steroidal analgesics except aspirin, history of taking proton pump inhibitors, previous history of stomach ulcers and sensitivity to non-steroidal analgesics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104092954N3**

Registration date: **2011-04-26, 1390/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-26, 1390/02/06

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Ssciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahroud University of Medical Sciences and Health and personal budget.

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of into wound Marcain with Naproxen suppository analgesic effects in patients with inguinal hernia operation in Shahid Modarres and Imam Hossein hospitals

Public title

Comparison of into wound Marcain with Naproxen suppository analgesic effects in patients with inguinal hernia operation

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All of the patients who scheduled for surgery, inguinal hernia, giving the consent form of participating in the research and had not clinical problems of anesthesia. Exclusion criteria: no consent form to participate in the research, clinical contraindication for anesthesia, clinical problems such as EF <20%, previous history of taking non-steroidal analgesics except aspirin, history of taking proton pump inhibitors, previous history of stomach ulcers and sensitivity to non-steroidal analgesics.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **198**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical sciences and health

Street address

Shahid Beheshti University of Medical sciences and health, Talaghani street, Tehran

City

Tehran

Postal code

Approval date

2008-07-22, 1387/05/01

Ethics committee reference number

87/263

2

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical

sciences and health

Street address

Shahroud University of Medical sciences and health, 7 Tir SQ, Shahroud

City

Shahroud

Postal code

3614773955

Approval date

2011-03-06, 1389/12/15

Ethics committee reference number

89/43

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

k40.0

ICD-10 code description

Bilateral inguinal hernia, with obstruction, without gangrene

Primary outcomes

1

Description

Pain evaluation of inguinal hernia ripare

Timepoint

First and sixty hours after surgery and the first and second days after surgery

Method of measurement

Examination and history with VAS system

Secondary outcomes

1

Description

Satisfaction evaluation

Timepoint

one ; two and three weeks after operation

Method of measurement

Examination and history

Intervention groups

1

Description

In the intervention group after inguinal hernia surgery by Lichtain eshtain methods, 2mg/kg Maracin solusion 0.125 into wound injected

Category

Treatment - Drugs

2

Description

In control group after inguinal hernia surgery by Lichtain eshtain methods, 500 mg Naproxen suppository (2 suppository 250 mg) was used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Dr.Mohammad Reza Abdoulhosseini

Street address

Shahid Modarres hospital, The end at Modarres street, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr.Mohammad Reza Abdoulhosseini

Street address

Imam Hossein hospital, The end at Imam street, Shahroud

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ; Shahroud University of Medical sciences and health

Full name of responsible person

Ahmad Khousravi

Street address

Vice chancellor for research, Shahroud University of Medical sciences and health, 7 Tir SQ, Shahroud

City

Shahroud

Grant name

پژوهشی

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research ; Shahroud University of Medical sciences and health

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

Shahroud University of Medical Sciences and Health

Full name of responsible person

Dr.Mohammad Bagher Sohrabi

Position

General Physician

Other areas of specialty/work

Street address

Imam Hossein hospital, The end at Imam street, Shahroud

City

Shahroud

Postal code

3616911151

Phone

+98 27 3334 2000

Fax

+98 27 3333 3902

Email

mb.sohrabi@shmu.ac.ir ; mb.sohrabi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences and Health

Full name of responsible person

Dr.Mohammad Reza Abdoulhosseini

Position

General Surgeon/ Asistant professor

Other areas of specialty/work

Street address

Imam Hossein hospital, The end at Imam street, Shahroud

City

Shahroud

Postal code

3616911151

Phone

+98 27 3334 2000

Fax

+98 27 3333 3902

Email

mra_75@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences and Health

Full name of responsible person

Dr.Mohammad Bagher Sohrabi

Position

General Physician/ Training director

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

Imam Hossein hospital, The end at Imam street,
Shahroud

City

Shahroud

Postal code

3616911151

Phone

+98 27 3334 2000

Fax

+98 27 3333 3902

Email

mb.sohrabi@shmu.ac.ir ; mb.sohrabi@yahoo.com

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