

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation the analgesic effect of Pergabalin on postoperative pain : A double blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of pregabalin on pain after inguinal hernia repair surgery by open method:

Design

There were 30 patients in the control group who were separated from the control group by dropping a coin. They received 75 mg of pregabalin 1 hour before the operation and 12 hours after it, and the control group was given a placebo at same time. Patient pain was measured at 0, 6, 12, 24 and 48 hours after surgery

Settings and conduct

The experiment was performed in Shahid Beheshti Hospital of Kashan. The people who gave medicine and placebo to the patients and the patients and the analyzer became blind were 30 people in the control group who received 75 mg of pregabalin 1 hour before the operation and 12 hours after it and the control group. At the same time, a placebo was given and then the patient's pain was measured at 6, 12, 24 and 48 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: open inguinal hernia repair surgery. Having an age between 20 to 65 years. Exclusion criteria: Pregnancy, history of pregabalin allergy, history of pregabalin treatment, history of syndrome Chronic pain and analgesia, alcohol and drug addiction, pethidine allergy,

Intervention groups

There were 30 patients in the control group who received 75 mg of pregabalin 1 hour before and 12 hours after the operation and the control group was given a placebo at the same time.

Main outcome variables

Age; sex; dosage of pethidine use; nausea and vomiting; pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200731048260N1**
Registration date: **2020-10-30, 1399/08/09**
Registration timing: **retrospective**

Last update: **2020-10-30, 1399/08/09**

Update count: **0**

Registration date

2020-10-30, 1399/08/09

Registrant information

Name

Benyamin Seyfari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2259 6152

Email address

seyfari@ptsoc.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

2020-03-05, 1398/12/15

Actual recruitment end date

2020-07-20, 1399/04/30

Trial completion date

2020-07-20, 1399/04/30

Scientific title

Evaluation the analgesic effect of Pergabalin on postoperative pain : A double blind randomized clinical trial

Public title

The analgesic effect of Pergabalin on post operative pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients candidate for open inguinal herniorraphy patients between 20 to 65 years old

Exclusion criteria:

pregnancy sensitivity to pergabalin addiction to drugs or alcohol sensitivity to pethedin uncontrolled blood pressure

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We used Excel , (Random between) , to divide 60 numbers in two groups and then used that order for patients to divide them in two different categories

Blinding (investigator's opinion)

Double blinded

Blinding description

patients were told there is an additional medication to evaluate how pain reponse to it the anilizers didnt know the group of patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, School of Medicine and Dentistry-Kashan University of Medi

Street address

General surgery group-kashan university of medical Sciences-ghotb ravandy bolvared

City

kashan

Province

Isfahan

Postal code

8715981151

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.132

Health conditions studied

1

Description of health condition studied

patients candidate for open inguinal herniorraphy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the amount of pain after inguinal herniorraphy

Timepoint

mearement of patients painimmediately after herniorraphy and 6,12,24,48 h after surgery

Method of measurement

Comparing the amount of pethedin recieved - Comparing pain rates by V.A.S (Visual Analog Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregabalin capsules (75 mg)c from Sami Saz Company were given to patients one hour before and 12 hours after surgery.

Category

Treatment - Drugs

2

Description

Control group: we gave placebos one hour before and 12 hours after surgery to this group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital of Kashan

Full name of responsible person

Benyamin Seyfari

Street address

unit 10 , apartment No 28 , Biglar Pur west alley,
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Email

benyaminseyfari1369@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafshe

Street address

Deputy of research and technology.Kashan university
of medical scienc.ghotbe ravandi boulevard

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Email

education @kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Benyamin Seyfari

Position

General surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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