Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

A clinical trial to compare the effectiveness of diclofenac in pain relief after inguinal hernia surgery with a non-treated group

Protocol summary

Study aim
To compare the effectiveness of diclofenac in pain relief after inguinal hernia surgery with a non-treated group.

Design
Sixty patients who were candidates for inguinal hernia surgery at the Department of Urology in Ghaem Hospital, Mashhad, Iran, were selected randomly using closed envelopes and assigned to control and intervention groups. A code is allocated to each of the participants.

Settings and conduct
Patients candidate for inguinal hernia surgery at the Department of Urology, Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the participants and the researcher responsible for data collection were unaware of the type of drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Not receiving any analgesics before surgery; not having allergy to diclofenac. Exclusion criteria: Surgery duration of more than one hour; history of hepatic and renal diseases; addiction or alcoholism or continuous use of any type of drug; gastrointestinal disorders; the use of analgesic drugs 24 hours before surgery.

Intervention groups
The intervention group receives diclofenac sustained-released 100 mg tablets with breakfast before surgery. The control group does not receive any analgesic drugs before surgery.

Main outcome variables
Evaluation and comparison of pain level based on visual analogue scale for pain at 1, 6 and 24 hours after surgery and the number of requests for morphine during the first 24 hours after surgery in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180708040378N1**
Registration date: **2018-07-28, 1397/05/06**
Registration timing: **prospective**

Last update: **2018-07-28, 1397/05/06**
Update count: **0**

Registration date
2018-07-28, 1397/05/06

Registrant information

Name
Behnoush Bahadoripour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 0000

Email address
bahadoripb901@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-06, 1397/06/15

Expected recruitment end date
2019-09-06, 1398/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of diclofenac in pain relief after inguinal hernia surgery with a non-treated group

Public title
The effect of diclofenac on pain relief after inguinal hernia surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Not receiving any analgesics before surgery not having allergy to diclofenac
Exclusion criteria:
Surgery duration of more than one hour history of hepatic and renal diseases addiction or alcoholism or continuous use of any type of drug gastrointestinal disorders the use of analgesic drugs 24 hours before surgery
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sixty patients who were candidates for inguinal hernia surgery at the Department of Urology in Ghaem Hospital, Mashhad, Iran, were selected randomly using closed envelopes and assigned to control and intervention groups. A code is allocated to each of the participants.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients candidate for inguinal hernia surgery at the Department of Urology, Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the participants and the researcher responsible for data collection were unaware of the type of drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2016-12-07, 1395/09/17
Ethics committee reference number
IR.MUMS.fm.REC.1395.297

Health conditions studied

1

Description of health condition studied
Inguinal hernia
ICD-10 code
K40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Pain level
Timepoint
1, 6 and 24 hours after surgery
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
The number of requests for morphine
Timepoint
The first 24 hours after surgery
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: This group receives diclofenac sustained-released 100 mg tablets with breakfast before surgery, the pain level will be measured based on visual analogue scale for pain at 1, 6 and 24 hours after surgery and the number of requests for morphine during the first 24 hours after surgery.
Category
Treatment - Drugs

2

Description
Control group: This group does not receive any analgesic drugs before surgery. Pain level will be measured based on visual analogue scale for pain at 1, 6 and 24 hours after surgery and the number of requests for morphine during the first 24 hours after surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Behnoush Bahadoripour
Street address
Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square
City
Mashhad
Province
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91766-99199
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bahadoripb901@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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Postal code
91375-345
Phone
+98 51 3841 1538
Email
vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Behnoush Bahadoripour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
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Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Behnoush Bahadoripour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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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

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

Informed Consent Form

Yes - There is 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

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

Behnoush Bahadoripour provides the analysis code to the applicants via email: bahadoripb901@mums.ac.ir

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