

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Email**

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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

**Contact**

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Mashhad University of Medical Sciences

**Full name of responsible person**

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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**