

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of Oral Magnesium and Oral Ketorolac on Postoperative Pain after Anorectal Surgery

#### Protocol summary

##### Study aim

Determining the comparative study of the effect of oral magnesium with oral ketorolac on pain after anorectal surgery

##### Design

randomized parallel Clinical trial with control group, double-blind, , phase 3, on 104 patients. For randomization, the method of randomization of permutation blocks has been used.

##### Settings and conduct

Patients who are candidates for anorectal surgery at Shahid Beheshti Hospital in Qom, Farabi Limited Surgery Center are divided into two groups: blind and randomized, divided into two intervention groups (receiving magnesium tablets) and the control group (receiving ketorolac tablets). The two drugs are compared to control postoperative pain in patients with anorectal disease. The clinical trial has two groups of control, parallel, double-blind, randomized, phase 3 on 104 patients. For randomization, the method of randomization of permutation blocks has been used.

##### Participants/Inclusion and exclusion criteria

Entry requirements; Candidate patients for anorectal surgery and obtaining informed consent and benefiting from the intervention Exit conditions; Possibility of injury or loss

##### Intervention groups

The first intervention group (receiving magnesium tablets), the second intervention group (receiving ketorolac tablets)

##### Main outcome variables

amount of pain (pain score)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120118008769N3**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

##### Registration date

2020-11-18, 1399/08/28

##### Registrant information

###### Name

Seyed Jalal Eshagh Hosseini

###### Name of organization / entity

Qom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25171181

###### Email address

j.hosseini@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-06, 1399/07/15

##### Expected recruitment end date

2021-01-06, 1399/10/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Oral Magnesium and Oral Ketorolac on Postoperative Pain after Anorectal Surgery

##### Public title

Determining the comparative study of the effect of oral

magnesium with oral ketorolac on pain after anorectal surgery

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

All patients who are candidates for anorectal surgery If the patient agrees to enter the study

##### **Exclusion criteria:**

Inflammatory bowel diseases Patient dissatisfaction complicated anal fistula Patients on sedative drug below eleven years old malignancy Perianal collections

#### **Age**

From **11 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider

#### **Sample size**

Target sample size: **104**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

After selecting the patients, the treatment will be assigned in two groups by the method of randomization of permutation blocks so that the number of samples in the two groups will be equal. For this purpose, four blocks of codes A and B will be made first. The selection of each block will also be random and will be done using dice. This launch will be performed 26 times to complete the assignment of patients to treatment groups. Assignment of treatment to the intervention and control groups will also be on a random basis(coin toss).

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Patients are randomly divided into two groups, one group receiving magnesium and the other group receiving ketorolac. ketorolac and magnesium are placed into identical pearls I. Recipients and physicians do not know the type of drug they receive. Only a third person who is not directly involved in the study has the codes of both types of drugs and ID of the patient in the groups.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Qom University of Medical Sciences

###### **Street address**

Qom University of Medical Sciences, Shahid Lavasani St

###### **City**

Qom

###### **Province**

Ghoom

###### **Postal code**

3713649373

##### **Approval date**

2020-10-06, 1399/07/15

##### **Ethics committee reference number**

IR.MUQ.REC.1399.184

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Comparative study of pain after anorectal diseases surgery with two types of ketorolac and magnesium pills

##### **ICD-10 code**

G89

##### **ICD-10 code description**

Pain, not elsewhere classified

### **Primary outcomes**

#### **1**

##### **Description**

amount of pain (pain score)

##### **Timepoint**

the 1,3,5,7 day after surgery,

##### **Method of measurement**

Visual analogue scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Intervention group 1: Group receiving 250 mg magnesium tablets from Galenus company that the patient takes one tablet daily from 3 hours before the operation for a week

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group: Intervention group 2: The group receiving ketorolac 10 mg tablets from Iran -Hormone company takes one tablet daily from 3 hours before the operation for a week

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital, farabi day clinics

**Full name of responsible person**

Seyed Jalal eshaqh Hoseini

**Street address**

Shahid Beheshti St ,ammar yaser St

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3719965654

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**Email**

Shahidbeheshti@muq.ac.ir

**Web page address**

<https://bmc.muq.ac.ir>

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

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deanofuniversity@muq.ac.ir

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**

No

**Title of funding source**

Qom University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Foreign

**Category of foreign source of funding**

Sponsor: country of origin

**Country of origin**

IR

**Type of organization providing the funding**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Seyed Jalal eshaqh Hoseini

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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**Person responsible for scientific inquiries**

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Ghous University of Medical Sciences

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Ghousm University of Medical Sciences

**Full name of responsible person**

Farzane Sadat Ghazi

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Shahid Beheshti Hospital ,Shahid Beheshti St.

**City****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