

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of Effectiveness of sodium diclofenac suppository in reduction of pain and dosage of narcotic in patients undergoing colonoscopy

Protocol summary

Summary

The aim of this study is to evaluate the effect of diclofenac suppository on dosage of narcotics during colonoscopy, in order to make sufficient tolerance to run a successful safety procedure and to obtain immediate consequence. This study will be done using 524 patients, after taking Informed consent, who candidate out-patient or in-patient colonoscopy for any reason. Patients with colonoscopy-phobia, history of previous intestinal surgery or inflammatory bowel disease or cardiopulmonary comorbidities or in conditions of contraindication of NSAIDs' usage (e.g. hypersensitivity), will be excluded. This study is a prospective, randomized, single-blind, placebo controlled. Besides the same dug regiments of midazolam and fentanyl for both groups before colonoscopy, Diclofenac suppository was administered to case group 30 minute before procedure. According to each group, Duration of colonoscopy & Narcotic dosage which are used during colonoscopy, will be documented. At the end of colonoscopy, patients pain will be scored by nurse, using visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092629976N1**

Registration date: **2016-10-10, 1395/07/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-10, 1395/07/19

Registrant information

Name

Reza Mohseni Ahangar

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8301

Email address

r.mohseni@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Babol University Of Medical Sciences

Expected recruitment start date

2016-08-21, 1395/05/31

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effectiveness of sodium diclofenac suppository in reduction of pain and dosage of narcotic in patients undergoing colonoscopy

Public title

The effect of diclofenac suppository in the use of drugs to reduce pain in patients undergoing colonoscopy

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:Colonoscopy candidate; consent to participate in the study Exclusion criteria:Patients who feared colonoscopy; patients with history of previous surgery; inflammatory bowel disease; cardiopulmonary comorbidities; history of NSAID hypersensitivity; in

situation of their contraindication

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 526

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University Of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Street, Babol

City

Babol

Postal code**Approval date**

2016-08-21, 1395/05/31

Ethics committee reference number

MUBABOL.REC.1395.130

Health conditions studied**1****Description of health condition studied**

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes**1****Description**

discomfort and pain

Timepoint

End of colonoscopy

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups**1****Description**

In the Control group, (5 mg, Daroupakhsh company, Iran) and Fentanyl (500 µg, Daroupakhsh company, Iran) with adding placebo was prescribed.

Category

Treatment - Drugs

2**Description**

In the intervention group, standard regimen include midazolam (5 mg, Daroupakhsh company, Iran) and Fentanyl (500 µg, Daroupakhsh company, Iran) with adding diclofenac suppository (100 mg, Daroupakhsh company, Iran) was prescribed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rouhani Hospital Of Babol

Full name of responsible person

Seyed Saeid Mohammadi Bonehi

Street address

Rouhani Hospital, Ganjafroz Street, Babol

City

Babol

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

Vice Chancellor For Research, Babol University Of Medical Sciences

Full name of responsible person

Ali Bijani

Street address

Babol University Of Medical Sciences, Ganjafroz Street, Babol

City
Babol

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor For Research, Babol University Of Medical Sciences

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
Babol University Of Medical Sciences

Full name of responsible person
Parviz Amri maleh

Position
Associated of Anesthesiolog

Other areas of specialty/work

Street address
Rouhani Hospital Of Babol, Ganjafrooz Street, Babol

City
Babol

Postal code

Phone
+98 11 3223 8284

Fax

Email
pamrimaleh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University Of Medical Sciences

Full name of responsible person
Seyed Saeid Mohammadi Bonehi

Position

Assistant Of Internal Medicine

Other areas of specialty/work

Street address
Rouhani Hospital, Ganjafrooz Street, Babol

City
Babol

Postal code
47176-41367

Phone
+98 11 3223 8284

Fax

Email
ssmmbb293@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babaol University Of Medical Sciences

Full name of responsible person
Reza Mohseni Ahangar

Position
Resident Of Internal Disease

Other areas of specialty/work

Street address
Rouhani Hospital, Ganjafrooz Street, Babaol

City
Babaol

Postal code
47176-41367

Phone
+98 11 3223 8284

Fax

Email
rohanresearch88@gmail.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