Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

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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, Ganjafrooz 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

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Rouhani Hospital, Ganjafroz Street, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research, Babol University Of Medical Sciences

Full name of responsible person

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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

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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