

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison among four methods of medication administration on pain control and satisfaction patients undergoing colonoscopy

Protocol summary

Summary

The aim of this study was to compare four types of medication in patients undergoing colonoscopy will be satisfaction and pain control. In this single-blind clinical trial and in a period of six months, 164 patients under the elective colonoscopy that inclusion criteria of at least 18 years of age non-emergency surgery and colonoscopy and without lack of acute bleeding in patients would be. If the patient needs more drug at the time of the colonoscopy, patient will be excluded from the study. Patients in 4 groups as follows: Group A (N = 41) patients receiving midazolam and fentanyl, Group B: (N = 41) patients receiving hydroxyzine and fentanyl, Group C: (N = 41) patients receiving Ktrlak, group D: (N = 41) patients receiving fentanyl and will be Ktrlak. The primary outcome of Pain and satisfaction during and immediately after colonoscopy with VAS scale and GHAA-9 scale collected and will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112221806N2**
Registration date: **2016-03-12, 1394/12/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-12, 1394/12/22

Registrant information

Name

Abolfazl Abdollahpoor

Name of organization / entity

Semnan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences - Research and development Vice

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison among four methods of medication administration on pain control and satisfaction patients undergoing colonoscopy

Public title

pain control and satisfaction patients undergoing colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :Non urgency of colonoscopy:At least 18 years of age for participant:Patient satisfaction:The lack of acute gastrointestinal bleeding:The patient is placed first under colonoscopy. Exclusion criteria:If the patient needs more medication at colonoscopy time:Sensitivity to patients' medication.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Kosar hospital in Semnan

City

semnan

Postal code

Approval date

2015-12-01, 1394/09/10

Ethics committee reference number

ir.semums.rec.1394.112

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description

Pain patients-Patient satisfaction

Timepoint

6 months

Method of measurement

standard questionnaires VAS and GHAA- 9

2

Description

Patients' satisfaction

Timepoint

6 months

Method of measurement

standard questionnaires VAS and GHAA- 9

Secondary outcomes

empty

Intervention groups

1

Description

In the group A used of drugs (midazolam + fentanyl) 2 mg/kg bolus intravenous fentanyl and midazolam 0.03 mg/kg as a bolus.

Category

Treatment - Drugs

2

Description

In the group B is used the drug (hydroxyzine + fentanyl) so that consumed two hours before colonoscopy, two tablets of 25 mg hydroxyzine and fentanyl 2 mg / kg intravenous bolus.

Category

Treatment - Drugs

3

Description

In the group C is injected intravenously drugs (ketorolac) so that 30 minutes before the colonoscopy 0.5mg / kg.

Category

Treatment - Drugs

4

Description

In the group D is injected intravenously drugs (ketorolac+ fentanyl) so that bolus intravenous fentanyl of 2 mg/kg, 30 minutes before the colonoscopy ketorolac 0.5 mg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Abolfazl Abdollahpor

Street address

Semnan

City

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

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

Street address

Department of Surgery Kowsar hospital

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

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Position

gastroenterologist

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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*