Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of sedative and analgesic effect of dexmedetomidin and fentanyl versus midazolam and fentanyl during colonoscopy: A double blind randomized clinical trial

Protocol summary

Summary

Objectives, The aim of this study is comparison of sedative and analgesic effect of dexmedetomidin and fentanyl versus midazolam and fentanyl during colonoscopy. Design, in a randomized clinical trial after approval of the ethics committee of the Babol University of Medical Sciences, 60 hospitalized patients, who candidate for colonoscopy were consecutively assigned into two equal groups. Setting and conduct, after taking written consent about type of anesthesia, to both groups, if the rescue dose is need, propofol 0.5 mg per kg as a bolus will administered. Patients, anesthesiologists, colonoscopist and the patient's examiner are blinded. The intervention group receives dexmedetomidine 1 mg per kg over 10 minutes and then 0.5 mg per kilogram per minute and fentanyl 0.5 microgram per kg and the control group receives midazolam 0.5 mg per kg maximum to 2.5 mg and fentanyl 0.5 microgram per kg before and during colonoscopy. Inclusion criteria: age 20-70 years; ASA class ≤ 3. Exclusion criteria: liver disease, kidney disease and addicted patients. Intervention, administration of dexmedetomidine 1 mg per kg over 10 minutes and then 0.5 mg per kilogram per minute and fentanyl 0.5 microgram per kg. Main outcome measures (variables), the depth of sedation based on the Ramsay scale, recovery time based on Aldret score equal to or greater than 9, the severity of pain according to the Visual Analogue Scale, colonoscopist satisfaction based on Likert scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603057752N9**
Registration date: **2016-06-26, 1395/04/06**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-06-26, 1395/04/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedative and analgesic effect of dexmedetomidin and fentanyl versus midazolam and fentanyl during colonoscopy: A double blind randomized clinical trial

Public title
Comparison of sedative and analgesic effect of dexmedetomidin and fentanyl versus midazolam and fentanyl during colonoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 20-70 years; ASA class ≤ 3
Exclusion criteria: age <20 years or> 70 years; heart disease (arrhythmia, aortic stenosis, ischemic heart disease,heart failure) ; liver disease (Child-Pugh classification C);kidney disease ; lack of patient cooperation;mental illness (major Depression, mania, psychosis); hypotension; hypertension; drug addiction.
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not 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 Siences
Street address
Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
City
Babol
Postal code
471764136
Approval date
2013-04-21, 1392/02/01
Ethics committee reference number
2306

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
Sedation
Timepoint
During and until 2 hours after colonoscopy
Method of measurement
Ramsay sedation scale

2

Description
pain
Timepoint
12 hours after colonoscopy
Method of measurement
Visoal analoge Scale

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
During and until 2 hours after colonoscopy
Method of measurement
mm hg

2

Description
Resoiratory rate
Timepoint
During and 2 hours after colonoscopy
Method of measurement
Number per minutes

3

Description
Heart rate
Timepoint
During and until 2 hours afer colonoscopy
Method of measurement
Number per minutes

Intervention groups

1

Description
administration of dexmedetomidine 1 mg per kg over 10 minutes and then 0.5 mg per kilogram per minute and fentanyl 0.5 microgram per kg
Category
Treatment - Drugs

2

Description
the control group receives midazolam 0.5 mg per kg maximum to 2.5 mg and fentanyl 0.5 microgram per kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rohani Teaching Hospital
Full name of responsible person
Amri Maleh Parviz
Street address
Rohany teaching Hospital, Ganjafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Moghaddamnia Ali
Street address
Babol University of Medical Sciences, Gangafrooz St, Daneshgah Square, Babol, Iran
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences, Vice chancellor for research
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
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Position
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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