Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comperative study of colonoscopic findings and effects in groups with/without traquilizing drug based on age and sex

Protocol summary

Study aim

The determination and comparison of the findings in both groups (with or with out sedative drugs)based on sex and age

Design

A clinical trial study including an applicable control group based on the society which is in line with other parallel groups.

Settings and conduct

This study will be conducted on patients of the colonoscopy ward at AL Zahra hospital and a private clinic in 2019. Patients are divided into two groups each containing 120. They will go through colonoscopy operations using different indications like digestive hemorrhage ,defecation and urine patterns, anemia,and iron deficiency.

Participants/Inclusion and exclusion criteria

The acceptance factors are being above 18 years and the existence of other standard indications of colonoscopy like digestive hemorrhage ,defecation and urine patterns, stomachache,anemia,iron deficiency ,colon cancer screening tests ,and the informed consent. The factors for non acceptance of the testes are as follow: Reluctance to continue the study, the non readiness of bowels, any background of colon surgeries , allergy to sedative drugs, cardiovascular instability, the size of colon tumor which can make the operation impossible.

Intervention groups

The ideal purpose of colonoscopy without sedatives is a meticulous examination of a patient without using any sedative drugs.it has many advantages.The studies reveal that a non sedative colonoscopy which is conducted meticulously can rarely cause any side effects and can include a large number of patients.

Main outcome variables

To determine the best method of colonoscopy in patients with the most findings and the least side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190105042246N1**
Registration date: **2019-02-01, 1397/11/12**
Registration timing: **prospective**

Last update: **2019-02-01, 1397/11/12**
Update count: **0**

Registration date

2019-02-01, 1397/11/12

Registrant information

Name

seid javad shariaat nabavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3552 3631

Email address

sjshn@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comperative study of colonoscopic findings and effects in groups with/without traquilizing drug based on age and sex

Public title
The study of not using the anesthesia in colonoscipic effects and findings
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Colonoscopy standard indications like digestive hemorrhage Any change in defecation and urination pattern , stomachache,anemia,iron deficiency,and pre cancer examination Bowels readiness to go through the colonoscopy operation Willingness to fill the informed consent
Exclusion criteria:
Reluctance to pursue the study Bowels are not ready The patients colon surgery background Allergy to sedative drugs Heart and arteries stability Colon tumor blockade which makes the surgery impossible
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Sequential sampling procedure and randomization is based on the table of random number
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The research ethics committee of the medical science university
Street address
Isfahan university of medicine,the centeral unit,Hezar Jarib Street, Isfahan,Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-12-22, 1397/10/01
Ethics committee reference number
397405

Health conditions studied

1

Description of health condition studied
colonoscopy with and without sedation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation in colonoscopy
Timepoint
Up to 24 hours after colonoscopy
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Use of sedation
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان الزهرا
Full name of responsible person
Ahmad Shavakhi
Street address
Soffeh Blvd.,Isfahan,Iran
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansor Siavash
Street address
Isfahan university of medicine,Hezar Jarib Street
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Phone
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Email
Arashrad57@yahoo.com
Web page address
http://mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ahmad shavakhi
Position
professor
Latest degree
Subspecialist
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Person responsible for updating data

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
It is necessary that all the applicants remain unknown.All the data including the side effects and advantages are to be published completely
When the data will become available and for how long
The data is promptly available after being published
To whom data/document is available
All the researchers, physicians,and anyone interested can send a request
Under which criteria data/document could be used
There will be some negotiations after receiving the data
From where data/document is obtainable
Applicants can send an email using ashavakhi@yahoo.com They can make calls using this number 09163163224 or go in person to the endoscopy ward of Alzahra Hospital
What processes are involved for a request to access data/document
There will be some negotiations with the applicant after sending the request.He will be informed about how to receive the data as soon as possible.
Comments