

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

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

Protocol summary

Study aim

The determination and comparison of the findings in both groups (with or without 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 comparative study of colonoscopic findings and effects in groups with/without tranquilizing drug based on age and sex

Public title

The study of not using the anesthesia in colonoscopic 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 central unit, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

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

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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

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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

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

Other areas of specialty/work

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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