

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Implementation of a population-level colonoscopic screening in first-degree relatives of colorectal cancer patients in Golestan province of Iran: Feasibility and Effectiveness

#### Protocol summary

##### Study aim

Results of the Golestan population-based cancer registry suggested a considerable increasing trend in incidence of colorectal cancer (CRC) in Golestan province during the last decade. CRC screening in high-risk individuals may be effective in reducing the CRC incidence and mortality. We aimed to assess the feasibility and effectiveness of implementation of colonoscopic screening in first-degree relatives of CRC patients in Golestan.

##### Design

This study is a phase III Parallel design controlled trial. This study includes two arms including intervention and control arms. The sample size of each arm is 500 subjects.

##### Settings and conduct

Subjects will be informed about importance of colonoscopy in CRC control. Subjects who accepted to perform colonoscopy will be recruited in intervention group and others, will be recruited in control arm. Subjects in intervention group will be referred for screening colonoscopy. Biopsy samples will be taken from abnormal pathologic lesions. Appropriate treatment will be considered for subjects with abnormal lesions. All participants in the intervention and control groups will be followed annually. If there is any possible evidence of developing cancer or death in each subject, the follow up team will collect supportive documents to define the exact cause of death or type of cancer. Participants in both groups will be followed for 5 years. At the end of the study, the outcomes of interest will be compared between intervention and control arms.

##### Participants/Inclusion and exclusion criteria

Inclusion: History of CRC in first degree relatives, age below 75 years Exclusion: History of malignancy, contraindications of colonoscopy, history of cirrhosis, renal failure.

##### Intervention groups

Colonoscopic examination, taking biopsy and pathological examination of abnormal lesions, Removal of polyps

##### Main outcome variables

Development of CRC and death from CRC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120225009124N3**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

##### Registration date

2018-12-24, 1397/10/03

##### Registrant information

##### Name

Gholamreza Roshandel

##### Name of organization / entity

Golestan University of Medical Sciences/ Golestan Research Center of Gastroenterology and Hepatology

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3225 1910

##### Email address

roshandel@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

**Expected recruitment end date**

2019-11-21, 1398/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Implementation of a population-level colonoscopic screening in first-degree relatives of colorectal cancer patients in Golestan province of Iran: Feasibility and Effectiveness

**Public title**

Colonoscopic screening for colorectal cancer

**Purpose**

Screening

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having history of colorectal cancer in first degree relative

Age lower than 75

**Exclusion criteria:**

Personal history of malignancy  
Contraindications of colonoscopy  
Personal history of cirrhosis  
Personal history of renal failure

**Age**

To 75 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 1000

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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**

Ethics committee of the National Institute for Medical  
Medical Research Development

**Street address**

West Fatemi

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۶۹۳۱۱۱

**Approval date**

2016-10-14, 1395/07/23

**Ethics committee reference number**

IR.NIMAD.REC.1395.011

**Health conditions studied****1****Description of health condition studied**

Colorectal cancer

**ICD-10 code**

C18.9

**ICD-10 code description**

Malignant neoplasm of colon, unspecified

**Primary outcomes****1****Description**

Incidence of Colorectal cancer

**Timepoint**

3 years

**Method of measurement**

All participants in the intervention and control groups will be followed annually. Each subject will annually be contacted by a telephone call, and questions about the subject's vital status and cancer incidence will be asked. If there is any possible evidence of developing cancer or death in each subject, the follow up team will collect supportive documents (from patient's hospital files,...) to define the exact cause of death or type of cancer.

**Secondary outcomes****1****Description**

CRC mortality

**Timepoint**

End of study follow up

**Method of measurement**

Telephone follow up and confirmation by reviewing patients' documents and files

**Intervention groups****1****Description**

Intervention group: Colonoscopy. The subjects will receive screening colonoscopic examination. In case of any abnormal pathological findings, appropriate

treatment will be considered for the subject

**Category**

Prevention

**2**

**Description**

Control group: No colonoscopy

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Omid Preventive Medicine and Health Promotion Center

**Full name of responsible person**

Gholamreza Roshandel

**Street address**

5th floor, Edalat 11, Mousavi hospital

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

National Institute for Medical Research Development

**Full name of responsible person**

Professor Reza Malekzadeh

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Number 21, Fatemi gharbi

**City**

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NIMAD@RESEARCH.AC.IR

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

National Institute for Medical Research Development

**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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Gholamreza Roshandel

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

Sayyad Shirazi Bolevard, Sayyad Shirazi hospital

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Assistant Professor

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Epidemiology  
**Street address**  
Sayyad Shirazi Boulevard, Sayyad Shirazi hospital  
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**Province**  
Golestan  
**Postal code**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
No - There is not a plan to make this available  
**Statistical Analysis Plan**  
No - There is not a plan to make this available  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
No - There is not a plan to make this available  
**Analytic Code**  
No - There is not a plan to make this available  
**Data Dictionary**  
No - There is not a plan to make this available