

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)

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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

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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

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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

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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

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

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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