

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Risk assessment counseling and screening in first degree relatives of colon cancer patients

Protocol summary

2015-09-04, 1394/06/13

Summary

This randomized controlled trial aims to measure the effectiveness of a counseling-based intervention in motivating index cases (counselees) in sharing cancer risk information with their first-degree relatives (FDRs), and whether the trial is effective in initiating/increasing the uptake of screening in FDRs of index patients who are registered in cancer registry system. Sample size includes 120 FDRs in intervention group, and 120 FDRs in control group. Intervention includes an in-person motivational counseling session with FDRs performed by psychosocial workers, plus consequent follow-up reminder calls. Motivational interview comprises individualized and interactive counseling which addresses risk assessment, screening barriers, and provides appropriate feedbacks to the counselees. Free colonoscopy and polypectomy will be offered to the both groups of study as well as adequate education on bowel prep and colonoscopy procedure for those who are willing to perform colonoscopy. Measures will be recorded at the baseline and maximum 6 months after the baseline. Primary outcome is performing colonoscopy in FDRs. Secondary outcome measures include FDRs' awareness, and knowledge on cancer, and their screening practice, barriers of screening.

General information

Acronym

Triple C (Colon Cancer Control) Trail

IRCT registration information

IRCT registration number: **IRCT2015061422711N1**

Registration date: **2015-09-04, 1394/06/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Hamideh Salimzadeh

Name of organization / entity

Digestive Diseases Research Institute, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8241 5492

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2016-07-01, 1395/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Risk assessment counseling and screening in first degree relatives of colon cancer patients

Public title

Colon cancer screening in high-risk population

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: Male and female siblings, parents, and children, of colon cancer patients who were 60 yrs. or

younger at the time of cancer diagnosis. Exclusion criteria: Performing total colonoscopy with in last year; personal history of colon cancer; personal history of irritable bowel diseases; age 76 and older

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

the Institutional Review Boards of Tehran University of Medical Sciences, and Digestive Diseases Re

Street address

Digestive Diseases Research Institute, Shariati Hospital, Tehran University of Medical Sciences, North Kargar Avenue 14666 Tehran, Iran

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Tehran

Postal code

1411713135

Approval date

2013-02-03, 1391/11/15

Ethics committee reference number

301/481

Health conditions studied

1

Description of health condition studied

colorectal cancer

ICD-10 code

C18, C19,

ICD-10 code description

Malignant neoplasm of colon, Malignant neoplasm of

rectosigmoid junction, Malignant neoplasm of rectum

Primary outcomes

1

Description

Screening Colonoscopy

Timepoint

0, 6months follow-up

Method of measurement

Colonoscopy report verification

Secondary outcomes

1

Description

knowledge, and awareness about colon cancer

Timepoint

0; 6 month follow-up

Method of measurement

Interview

2

Description

knowledge, and awareness on screening tests of colon cancer

Timepoint

0; 6 month follow-up

Method of measurement

Interview

Intervention groups

1

Description

Intervention includes below: • Tailored massages via phone counseling • Interactive and in-person counseling about screening barriers • Individualized motivational interview • Consequent Follow-up reminder calls

Category

Early detection

2

Description

One parallel control group of usual care will be designed in this study. That is, counselees (index patients or FDRs) in control group will receive a simple doctor recommendation that screening is necessary should be done in FDRs, and that they better to inform their FDRs, as happened in routine care, the main source of recommendation is doctor's recommendation. Usually index patients during their treatment are informed by doctors about the risk of developing cancer in their relatives and the significance of screening or early detection among their relatives.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Digestive Diseases Research Institute

Full name of responsible person

Dr. Hamideh Salimzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Alireza Delavari

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Shariati Hospital, North Kargar Avenue 14666 Tehran,
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Tehran

Grant name

طرح پژوهشی

Grant code / Reference number

301/481

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Name of organization / entity

Digestive Diseases Research Institute, Tehran
University of Medical Sciences,

Full name of responsible person

Dr Hamideh Salimzadeh

Position

Phd in Health Education/Assistant Professor

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

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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