

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effects of a non-endoscopic screening program on esophageal cancer incidence and mortality in Golestan province of Iran- a randomized controlled trial

Protocol summary

Summary

Objectives: Golestan province located in Northern Iran has been known as a high-risk area for esophageal squamous cell carcinoma (ESCC). Results of a recent study from this region suggested that capsule sponge cytology is a feasible and valid primary method for ESCC screening in this region. The aim of this study is to assess the effects of implementation of a non-endoscopic EC screening program on outcomes of interest in an asymptomatic high-risk population in Golestan Province, Iran. **Design:** This is a randomized controlled trial. **Setting and conduct:** This study will be conducted on participants of Golestan Cohort Study (GCS). We will use a cluster randomized sampling method. Participants will be recruited in two groups including intervention and control groups. All participants will be followed for 5 years. After finishing the follow up, outcomes of interest will be compared between the two groups. **Participants:** 12000 GCS members will be recruited and randomly allocated in intervention (6000 subjects) or control (6000 subjects) groups. Subjects with age higher than 50 years and Living in Eastern Golestan for at least 10 years will be recruited. Subjects with history of malignant disease, liver cirrhosis, or chronic renal failure will be excluded. **Interventions:** In intervention group, capsule sponge examination will be performed to detect precancerous lesions in the esophagus. Subjects with abnormal lesions will be referred for further diagnosis and treatment. **Control group** will be recruited without any intervention. **Main outcome measures variables:** The primary outcomes include incidence of ESCC, death from ESCC and death from all causes.

General information

Acronym

NESP

IRCT registration information

IRCT registration number: **IRCT201501179124N2**

Registration date: **2015-02-15, 1393/11/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

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

Digestive Disease Research Institute, Tehran University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a non-endoscopic screening program on esophageal cancer incidence and mortality in Golestan province of Iran- a randomized controlled trial

Public title

Esophageal cancer screening in Golestan province

Purpose

Screening

Inclusion/Exclusion criteria

Major criteria for inclusion: Age higher than 50 years; Living in Eastern Golestan for at least 10 years Major criteria for exclusion: History of malignant disease; liver cirrhosis; chronic renal failure

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **12000**

Randomization (investigator's opinion)

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 Tehran University of Medical Sciences

Street address

Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2015-01-12, 1393/10/22

Ethics committee reference number

93-03-37-27139-135145

Health conditions studied

1

Description of health condition studied

Esophageal Cancer

ICD-10 code

C15.9

ICD-10 code description

Malignant neoplasm of oesophagus

Primary outcomes

1

Description

Incidence of esophageal squamous cell carcinoma

Timepoint

After finishing the study

Method of measurement

Personal interview and reviewing patients' medical files

2

Description

Death from esophageal squamous cell carcinoma

Timepoint

After finishing the study

Method of measurement

Personal interview and reviewing patients' medical files

3

Description

Death from all causes

Timepoint

After finishing the study

Method of measurement

Personal interview and reviewing patients' medical files

Secondary outcomes

1

Description

Incidence of esophageal adenocarcinoma

Timepoint

After finishing the study

Method of measurement

Personal interview and reviewing patients' medical files

2

Description

Change in quality of life

Timepoint

Before starting and after finishing the study

Method of measurement

Using a standard quality of life questionnaire

Intervention groups

1

Description

Intervention group: Capsule sponge examination for collecting cytological sampling form the esophagus

Category

Early detection

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Atrak clinic

Full name of responsible person

Dr Gholamreza Roshandel

Street address

Second floor, KhatamolAnbia hospital, Ring road, Gonbad

City

Gonbad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Yunesian

Street address

Qods avenue, Keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

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

Full name of responsible person

Dr Gholamreza Roshandel

Position

PhD in epidemiology

Other areas of specialty/work

Street address

10th Azar alley, 5th Azar street

City

Gorgan

Postal code

Phone

00891732340835

Fax

Email

roshandel_md@yahoo.com; roshandel@goums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Digestive Disease Research Institute, Tehran University of Medical Sciences

Full name of responsible person

Professor Reza Malekzadeh

Position

Sub-specialty in Gastroenterology

Other areas of specialty/work

Street address

Shariati hospital, North Karegar avenue

City

Tehran

Postal code

Phone

+98 21 8241 5104

Fax

Email

malek@ams.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan Research center of Gastroenterology and Hepatology, Golestan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Roshandel

Position

PhD in Epidemiology

Other areas of specialty/work

Street address

10th Azar alley, 5th Azar street

City

Gorgan

Postal code**Phone**

00

Fax**Email**

roshandel_md@yahoo.com

Web page address**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*