Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 yearswill 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 Bulevard
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 bulevard
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 cencer of Gastroenterology and Hepatology, Golestan University of Medical Sciences
Full name of responsible person
Dr Gholamreza Roshandel
Position
PhD in Epidemilogy
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