

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Low-dose Aspirin in the Prevention of Gastric Cancer

Protocol summary

Study aim

Evaluation of low-dose aspirin in the prevention of gastric cancer (GC)

Design

Two arms parallel-group simple randomized clinical trial (phase 3,4) to assessment prevention of gastric cancer event. . The subjects (21000 persons) will first be tested for Helicobacter pylori using a stool antigen test. Affected people receive standard drug treatment. After being infected with Helicobacter pylori, they are randomly divided into two groups. The first group is given a daily aspirin tablet of 81 mg Parsdarou company and the control group is given a placebo prepared by the same factory. After signing the consent form, individuals will enter the study and will be followed up for 10 years.

Settings and conduct

Ardabil is an area with a high incidence of gastric cancer. In the University digestive disease research center, the group of people is randomly selected and invited using the city's household health record. After obtaining consent, individuals are evaluated for Helicobacter pylori and treated if necessary. They are then randomly divided into intervention and control groups and followed for ten years for gastric cancer. Participants and follow-up and statistics groups are blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Without a history of gastric cancer
Resident in Ardabil Age 35 - 70 Willing to undergo the treatments and procedures described in the protocol
Willing to provide necessary biological specimens Willing to sign an informed consent form
Exclusion Criteria:
History of Severe dyspepsia, peptic ulcer, and GI bleeding/ perforation
History of NSAID gastritis
Known allergy to any of the study medications
Known medical conditions that could limit life expectancy

Intervention groups

Asprin and placebo group

Main outcome variables

Gastric cancer event

General information

Reason for update

The new sample size (21000 participants) was calculated and applied according to the updated information and executive restrictions.

Acronym

TELAPGC

IRCT registration information

IRCT registration number: **IRCT201105082032N3**

Registration date: **2017-04-21, 1396/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-03, 1401/10/13**

Update count: **1**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

Farhad Pourfarzi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

- Ministry of Health and Medical Education - Ardabil University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2020-03-11, 1398/12/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Low-dose Aspirin in the Prevention of Gastric Cancer

Public title

The effect of Low-dose Aspirin in the Prevention of Gastric Cancer

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Living in the province for ten years Negative pregnancy test Willing to participate in the study Willing to provide biological specimens Willing to sign an informed consent form

Exclusion criteria:

No history of Gastric cancer History of Severe dyspepsia, peptic ulcer and GI bleeding/ perforation History of NSAID gastritis Known allergy to any of the study medications Known medical conditions that could limit life expectancy (eg. HIV/AIDS, congestive heart failure, renal failure, hepatic failure, current or prior malignancy, any other chronic disease that limits function) Prior esophageal malignancy, gastric ulcer or a gastrectomy (full or partial)

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **21000**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants were randomly assigned to either aspirin or placebo groups with a 1:1 allocation ratio using permuted block randomization. Randomization was stratified by the initial HP status of subjects, baseline presence of intestinal metaplasia, and presence of two or more GC risk factors, to ensure recruitment balance between the two arms of the study. The permuted block sequence was generated with a block size of four. T

Blinding (investigator's opinion)

Double blinded

Blinding description

The provided medications, including aspirin and placebo, are small-sized white tablets. Aspirin and placebo bottles are both completely the same and labeled as "Artamed".

Both bottles contain 120 tablets, and the manufacturer prints a code on each bottle which can be used to determine the type of medication inside them. The codes were concealed in sealed and opaque envelopes with printed corresponding randomization numbers on them and kept safely in the study site with the personal investigator. DDRI provides and relabels the study drug and placebo to maintain the masking of the contents. The trial participants and care providers are blinded to the allocation. Staff independent of the study conduction enter data in the database using participants' randomization codes so that outcome assessors and data analysts remain unaware of the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardabil University of Medical Sciences

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Daneshgah St

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Ardabil

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5618985991

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.ARUMS.REC.1395.135

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

Gastric Cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

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

Gastric Cancer

Timepoint

visits at first, 12 weeks, every 4 months, 5 years and 10

years
Method of measurement
Age standardized Incidence and Mortality Rate

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Aspirin 81 mg (oral) Parsdarou company once daily

Category

Treatment - Drugs

2

Description

Placebo (Control):Tablet placebo (oral) Parsdarou company once daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Cohort Studies Center

Full name of responsible person

Dr. Farhad Pourfarzi

Street address

Digestive Disease Research Center, 30 Tir St. Ardabil

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<https://research.arums.ac.ir/en/research-centers/ddrc/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry of Health and Medical Education

Full name of responsible person

Dr. Reza Malekzadeh

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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

Ministry of Health and Medical Education

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

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

Ardabil University of Medical Sciences

Proportion provided by this source

10

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

3

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
962245

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
40

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
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available