

# 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)

###### Phone

+98 45 3325 9011

###### Email address

f.pourfarzi@arums.ac.ir

##### 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

**Street address**

Daneshgah St

**City**

Ardabil

**Province**

Ardabil

**Postal code**

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

##### City

اردبیل

##### Province

Ardabil

##### Postal code

5613658115

##### Phone

+98 45 3325 9011

##### Fax

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##### Email

farhad.pourfarzi@gmail.com

##### Web page address

<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

##### Street address

Ministry of Health and Medical Education

##### City

Tehran

##### Province

Tehran

##### Postal code

1467664961

##### Phone

+98 21 8145 5152

##### Email

dr.reza.malekzadeh@gmail.com

#### 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

Dr. Shahram Habibzadeh

##### Street address

Daneshgah St.

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##### Province

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##### Phone

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s.habibzadeh@arums.ac.ir

##### Web page address

#### 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**  
Dr. Reza Malekzadeh  
**Street address**  
NIMAD, Besat St.  
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Tehran  
**Province**  
Tehran  
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**Phone**  
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**Fax**  
**Email**  
nimad@research.ac.ir  
**Web page address**  
<http://nimad.ac.ir/>

#### **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**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Dr. Farhad Pourfarzi  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Cancer Epidemiology

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### **Person responsible for scientific inquiries**

#### **Contact**

**Name of organization / entity**  
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**Full name of responsible person**  
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Principal Investigator / Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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### **Person responsible for updating data**

#### **Contact**

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**Full name of responsible person**  
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**Position**  
Professor  
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**Other areas of specialty/work**  
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**Web page address**

## 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