

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effect of carvedilol in the prevention of cardiovascular complications induced by (5fu (5Fluorouracil) therapy in gastrointestinal cancer (GI) patients

Protocol summary

Study aim

We aim to evaluate the efficacy of carvedilol on preventing 5fu (5 fluorouracil) induced cardiovascular complications in patients with gastrointestinal cancer

Design

In this randomized triple-blind study Clinical trial with control group, phase 3 on 60 patients, block randomization method was used for randomization.

Settings and conduct

This study will be performed on 60 patients between 18 and 80 years old with gastrointestinal, in Imam Khomeini Hospital in Ardabil. Patients would be selected to participate in the study according to the inclusion and exclusion criteria. Patients' identification; stage of cancer, ECG, troponin level, and primary echocardiographic findings would be registered in the questionnaire. The patient's ECG, troponin level, and echocardiography would be checked before and after all 3 courses of chemotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-All patients with gastrointestinal cancer who are in the age range of 18 to 80 years and are treated with 5fu 2- LVEF > 50% Exclusion criteria: 1. Patients with a history of (PCI, CABG, and Plavix use). 2- valve stenosis and cardiomyopathy 3. Ischemic signs in ECG 4. At any stage of the study suffer from acute myocardial ischemia.

Intervention groups

First group will receive carvedilol 6.25 twice a day and second group will receive placebo twice a day from two weeks prior to chemotherapy till one week after chemotherapy.

Main outcome variables

The main outcome of the study is cardiotoxicity occurrence during or after chemotherapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200907048646N1**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

reza fereydoonzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 0326

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-20, 1399/06/30

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of carvedilol in the prevention of cardiovascular complications induced by (5fu (5Fluorouracil) therapy in gastrointestinal cancer (GI) patients

Public title

Evaluation of the effect of carvedilol in patients with gastrointestinal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All gastrointestinal cancer patients in the age range of 18 to 80 years old underwent 5FU therapy. LVEF (left ventricular Ejection Fraction)>50%

Exclusion criteria:

Patients with IHD (history of PCI, CABG, and Plavix consumption) Mitral stenosis and cardiomyopathy ECG changes characteristic to ischemia (ST-elevation more than 0.5mm and ST-depression more than 1 mm) Acute myocardial ischemia at any stage of the study (ECG changes characteristic to ischemia, increased cardiac enzymes, or ischemic manifestations on echocardiography).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple-blinded study. In fact, both Carvedilol and Placebo have been placed in a box of the same color and size by the pharmacist. The physician and Analyser do not know about the content of the boxes which have A, B on them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of medical science

Street address

Imamkhomeyni Hospital, Noi Aghdam street

City

Ardabil

Province

Ardabil

Postal code

5541736637

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.ARUMS.REC.1398.374

Health conditions studied

1

Description of health condition studied

Gastrointestinal cancers (Esophageal cancer, Gastric cancer, Pancreatic cancer, Colon cancer)

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

Percentage of patients with gastrointestinal cancer with cardiac complications

Timepoint

Evaluation of the patient's cardiac condition before the intervention and during chemotherapy at the end of all 3 courses

Method of measurement

ECG, Troponin, Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive carvedilol 6.25 mg twice a day two weeks before chemotherapy till one week after chemotherapy.

Category

Treatment - Drugs

2

Description

Control group: in this group. placebo will be given twice a day from two weeks prior to chemotherapy till one week after chemotherapy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamkhomeyni Hospital

Full name of responsible person

Effat Iranijam

Street address

Imamkhomeyni Hospital, Noi Aghdam street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Farhad Pourfarzi

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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

20

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

Effat Iranijam

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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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