

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Polypill V on cardiovascular events in patients with breast and colorectal cancer

Protocol summary

Study aim

Determining the effect of Polypill V on cardiovascular events in patients with breast and colorectal cancer

Design

Two arm parallel group randomised clinical trial with Stratification randomization.

Settings and conduct

This study is a parallel randomized controlled clinical trial that is performed in patients with breast and colorectal cancer who have recently undergone surgery or take two sessions of cancer treatment without history of CVD in Isfahan. After coordination with oncologists, patients are referred to the research institute, then electrocardiography, echocardiography and blood tests are performed for them and a questionnaire is completed. Statistical analysis using descriptive statistics and T-test, Anova, COX regression and Kaplan Mayer survival analysis also performs extended cox if necessary.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Study participants signed written informed consent Cancer patients with no history of CVD Having EF>50 Exclusion criteria: Having Contraindications to one of the components of the polypill V

Intervention groups

Patients with breast cancer and colorectal cancer

Main outcome variables

Incidence of heart failure (systolic or diastolic) Incidence of symptomatic arrhythmia Incidence of acute coronary artery syndromes Incidence of stroke Death due to cardiac events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201110049329N1**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

zamaneh vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3611 5101

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zamane.vafaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-21, 1400/02/31

Expected recruitment end date

2025-05-21, 1404/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Polypill V on cardiovascular events in patients with breast and colorectal cancer

Public title

The effect of Polypill V on cardiovascular events

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Study participants signed written informed consent,
Cancer patients with no history of CVD, Having EF>50

Exclusion criteria:
Having Contraindications to one of the components of the polypill V

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **440**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified randomization is used for random allocation of patients. In breast cancer patients have three stratum :
1- The group that take anthracycline alone (60%) in which 78 people take drug and 78 people take usual care, 2- The group that take anthracycline and bevacizumab (20%) In this group, 26 people take drug and 26 people take usual care. 3 - The group that does not take anthracycline (20%) In this group, 26 people take drug and 26 people take usual care. In colon cancer patients have two stratum : 1 - Group that take chemotherapy (80%) In this group, 72 people take drug and 72 usual care. 2- Group that only undergoes surgery (20%) In this group, 18 people take drug and 18 people take usual care. Randomization is done using randomization software, the output of the software is from number 1 to 440, which indicates that each person who in the study in each stratum is in drug group or usual care. After the patient enrollment, according to list, patient take polypill V.

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
Vice-Chancellor in Research Affairs-Medical University

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Floor 2, Bleeding No.4, Isfahan University of M

Hezarjerib Street

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Isfahan

Postal code
8174673461

Approval date
2020-08-09, 1399/05/19

Ethics committee reference number
IR.MUI.MED.REC.1399.383

Health conditions studied

1

Description of health condition studied
Cardiovascular events

ICD-10 code
QA02

ICD-10 code description
Medical observation or evaluation for suspected diseases or conditions, ruled out cardiovascular diseases

2

Description of health condition studied
Breast Cancer

ICD-10 code
2C60

ICD-10 code description
Carcinoma of breast, specialised type

3

Description of health condition studied
Colorectal Cancer

ICD-10 code
2B91.Z

ICD-10 code description
Malignant neoplasms of rectosigmoid junction, unspecified

Primary outcomes

1

Description
Systolic and diastolic heart failure

Timepoint
6 months and one year after the intervention

Method of measurement
Ecocardiography

2

Description
Symptomatic arrhythmia

Timepoint
6 months and one year after the intervention

Method of measurement
Clinical symptoms, Ecocardiography

3

Description

Acute coronary syndromes

Timepoint

6 months and one year after the intervention

Method of measurement

Ecocardiography

4

Description

Stroke

Timepoint

6 months and one year after the intervention

Method of measurement

Brain CT scan

5

Description

Cardiovascular mortality

Timepoint

6 months and one year after the intervention

Method of measurement

Death certificate

Secondary outcomes

1

Description

Echocardiographic changes

Timepoint

6 months and one year after the intervention

Method of measurement

Echocardiography

2

Description

Changes in blood pressure

Timepoint

6 months and one year after the intervention

Method of measurement

Digital BP monitor

3

Description

Change in lipids

Timepoint

6 months and one year after the intervention

Method of measurement

Blood test

4

Description

Change CRP

Timepoint

6 months and one year after the intervention

Method of measurement

Blood test

5

Description

Hospitalization for cardiac events

Timepoint

6 months and one year after the intervention

Method of measurement

Hospitalization file

6

Description

Quality of life

Timepoint

6 months and one year after the intervention

Method of measurement

WHO Questionnaire

Intervention groups

1

Description

Intervention group: The intervention is Polypill V, which includes aspirin (81 mg), valsartan (40 mg), atorvastatin (20 mg) and hydrochlorothiazide (5.12 mg). This pill is produced Alborz Company and is taken once a day after dinner.

Category

Treatment - Drugs

2

Description

Control group: patients are followed for cardiovascular events

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Isfahan Cardiovascular Research Institute

Full name of responsible person

Dr Nizal Sarrafzadegan

Street address

Chamran Heart Center, Shahid Rahmani Alley,
Moshtagh Sevom Steet, Isfahan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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?**

No

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Nizal Sarrafzadegan

Position

Head of the Cardiovascular Research Institute

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Nizal Sarraf zadegan

Position

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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

Not applicable

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