

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of captopril added to standard chemotherapy regimen containing capecitabine in the prevention of hand and foot syndrome in patients with colorectal

Protocol summary

Study aim

Determining the effect of Captopril in the prevention and treatment of hand and foot syndrome in patients with colorectal cancer undergoing chemotherapy with capecitabine

Design

In this study, randomized double-blind clinical trial of phase three with the control group, 66 patients undergoing chemotherapy with Capecitabine will be distributed in two groups. In the first group of Captopril and in the second group of placebo were prescribed and the incidence of hand and foot syndrome in both groups was determined and compared.

Settings and conduct

This study is a double-blind randomized clinical trial conducted in 2021 in Seyed Al-Shohada Hospital in Isfahan. This study is a double-blind study and the patient and the researcher are unaware of the type of drug received.

Participants/Inclusion and exclusion criteria

In this study, patients with colorectal cancer undergoing chemotherapy with capecitabine. Patients taking drugs affecting foot syndrome as well as patients with kidney and liver disease and hypertension sensitive to captopressil are not included in the study.

Intervention groups

Patients in the intervention group were prescribed two 25 mg captopril tablets daily (manufactured by Elixir Pharmacy under the brand name Captopril Elixir) and in the control group, two placebo tablets daily, which have a similar appearance to 25 mg captopril, were prescribed one week before. The start of chemotherapy was prescribed until the end of the third period.

Main outcome variables

Hand and foot syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N50**

Registration date: **2020-12-02, 1399/09/12**

Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**

Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of captopril added to standard chemotherapy regimen containing capecitabine in the prevention of hand and foot syndrome in patients with colorectal
Public title	Evaluation of the effect of captopril in the prevention of hand and foot syndrome and in patients with colon cancer
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Colorectal cancer candidate for chemotherapy with capsaicin Patient consent to participate in the study
Exclusion criteria:	Taking drugs that affect the incidence of hand and foot syndrome, including taking second-generation antipsychotics Suffering from metabolic diseases including diabetes and kidney disease Having high blood pressure Sensitivity to Captopril
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 66
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization of patients between the intervention and control groups is done using random allocation software. In this software, the total sample size and number of nodes are entered into the software. The output of Shalam software is a list that randomly distributes patients in groups 1 and 2. Patients are divided into two groups according to the time of referral according to the list of the mentioned group until the end of sampling.
Blinding (investigator's opinion)	Double blinded
Blinding description	This study is performed in double blinds and patients and researchers are unaware of the type of drug received. Drugs are prepared in coded form in similar packages and are provided to the executor for prescription to patients. Outcome assessment is also done by someone who is not in the study.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Isfahan University of Medical Sciences
Street address	Isfahan University of Medical Sciences, Hezarjerib hospital
City	Isfahan
Province	Isfahan
Postal code	8434193474
Approval date	2019-01-20, 1397/10/30
Ethics committee reference number	IR.MUI. MED.REC.1397.025
Health conditions studied	
1	
Description of health condition studied	Colorectal cancer
ICD-10 code	C18-19
ICD-10 code description	Malignant neoplasm of colon and rectum
Primary outcomes	
1	
Description	Hand and foot syndrome
Timepoint	Every 3 weeks
Method of measurement	Physical examination
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: Patients receiving 25 mg of captopril tablets daily for six weeks
Category	Prevention

2

Description

Control group: A placebo recipient who looks similar to Captopril and contains flour once a day for 6 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyedoshohada Hospital

Full name of responsible person

Noushin Nazeminejad

Street address

Seyedoshohada hospital, Khayam street, Isfahan

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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?

Yes

Title of funding source

Esfahan 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

Mahnaz Roayaei

Position

Assistant profesor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

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Full name of responsible person

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Statistical consultant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to a government agency and cannot be published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available