# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

12 Jun 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 capsitabin

**Design**

In this study, randomized double-blind clinical trial of phase three with the control group, 66 patients undergoing chemotherapy with Capesitabin will 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 capsaicin. 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)

**Phone**

+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**
Isfehan

**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
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3668 5555
**Email**
nooshin.nazemi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Haghjoo
**Street address**
Research Deputy, Isfahan University of Medical Sciences, Hezarjerib street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3792 3070
**Email**
sh_haghjoo@med.mui.ac.ir
**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
**Street address**
Khayyam street, Seyedoshohada hospital
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3668 5555
**Email**
mahnaz.roayaei5@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Nadia Najafizadeh
**Position**
Assistant profesor
**Latest degree**
Specialist
**Other areas of specialty/work**
Radiotherapy
**Street address**
Khayyam street, Seyedoshohada hospital
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3669 5555
**Email**
n_najafizadeh@med.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Ali Mehrabi

**Position**
Statistical consultant

**Latest degree**
Master

**Other areas of specialty/work**
Epidemiology

**Street address**
School of Medicine, Isfahan University of Medical Sciences, Hezarjerib street

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8434193474

**Phone**
+98 31 3356 3466

**Email**
al.mehrabi@gmail.com

## 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