

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of efficacy of topical formulation of silymarin in prevention and management of hand-foot syndrome induced by capecitabine in patients with gastrointestinal malignancies

Protocol summary

Summary

This study is a prospective, triple-blind, randomized clinical trial to compare the effects of topical silymarin 1% with placebo in prevention of hand foot syndrome induced by capecitabine in patients with gastrointestinal cancers (esophagus, gastric, colorectal). In this study 40 patients with gastrointestinal tract cancer diagnosis referring to oncology ward of Imam Reza hospital, Mashhad, Iran who decided to be treated with chemotherapy regimen included capecitabine have been selected based on random number table to receive topical silymarin gel 1% or placebo gel which produced by Goldaroo company. The placebo/silymarin formulations are defined as A or B by producer and the oncologist, pharmacy student and clinical pharmacist who analyzed the data are not aware of formulation type. They should use half knuckle of cream on the soles of the feet and a knuckle of cream on the palm of the hands twice a day. At the beginning of the study, we record patients' characteristics like age, gender, weight, height, body surface area, past medical and drug history, type of chemotherapy regimen and its duration. In both groups, patients are followed regarding hand foot syndrome occurrence every three weeks for nine weeks based on WHO grading scale. The patients with grade 3 or 4 (based on WHO grading scale) of HFS who need to decrease the dosage of capecitabine will be excluded from this trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110730621N1**

Registration date: **2017-01-02, 1395/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

Farzaneh Rezazadeh

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 584 5302

Email address

rezazadehf901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of topical formulation of silymarin in prevention and management of hand-foot syndrome induced by capecitabine in patients with gastrointestinal malignancies

Public title

evaluation of topical silymarin on dermal side effect induced by capecitabine in patients with gastrointestinal cancers

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: age between 18-70 years- gastrointestinal tract malignancies who treated with chemotherapy regimen included capecitabine exclusion criteria: hepatic failure (LFT >5times of upper limit normal, or >3time of upper limit normal and symptoms), renal failure (GFR<30), severe infection requiring antibiotic therapy, dissatisfaction of patient, history of allergy to silymarin, autoimmune disease history, diabetes mellitus, concomitant use of NSAIDs, corticosteroids, other immunosuppressive drugs

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Ghoreishi building, daneshgah street

City

mashhad

Postal code

13944-91388

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

IR.MUMS.REC.1395.384

Health conditions studied

1

Description of health condition studied

Hand-foot syndrome

ICD-10 code

R21

ICD-10 code description

Rash and other nonspecific skin eruption

Primary outcomes

1

Description

hand-foot syndorme occurrence

Timepoint

at the beginning of the study, at the end of third week after intervention, at the end of 6th week after intervention, and at the end of the 9th weekafter intervention

Method of measurement

grade of the WHO criteria for classification of hand-foot syndrome

Secondary outcomes

1

Description

hepatic transaminase level

Timepoint

At the beginning of the study, at the end of the third, 6th, and 9th weeks

Method of measurement

laboratory

2

Description

serum creatinine and BUN level

Timepoint

At the beginning of the study, at the end of the third, 6th, and 9th weeks

Method of measurement

laboratory

Intervention groups

1

Description

Silymarin topical gel 1% which produced by Goldaru Company, two times a day, one finger tip unit for soles of foote and half of a finger tip unit for soles of the hands for 9 weeks.

Category

Prevention

2

Description

placebo gel of silymarin which produced by Goldaru company, two times a day, one finger tip unit for soles of foets and half of a finger tip unit for soles of the hands for 9 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospita, Hematology and Oncology ward

Full name of responsible person

Dr Abolghasem Allahyari

Street address

Imam Reza Hospital- Imam Reza Squ.- Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Isar clinic

Full name of responsible person

Dr Abolghasem Allahyari

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi, Vice-chancellor of Research

Street address

E-Campus University of Mashhad-Iran Vakil Abad

City

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Science-Pharmacy faculty

Full name of responsible person

Dr Mohsen Tafaghodi

Position

Vice chancellor foe research, Mashhad University of Medical Science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Mashhad University of Medical Science-Pharmacy faculty

Full name of responsible person

Farzaneh Sadat Rezazadeh Shojaei

Position

Professional Doctorate of pharmacy student

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty