

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigation of the efficacy of a topical dosage form consisting calendula officinalis L., Matricaria recutita L. and Salvia officinalis L extracts in reducing Fluoropyrimidines induced Hand-Foot Syndrome in cancerous patients

Protocol summary

Summary

The purpose of this study is to introduce a suitable topical product of combination from calendula officinalis, matricaria chamomilla and salvia officinalis to improve Hand-foot syndrome symptoms in cancer patients who are taking Fluoropyrimidine drugs. The study population is cancer patients who are taking IV injection of 5-fluorouracil or oral Capecitabine and showing hand-foot syndrome. These patients are entered in study with consent. Patients in the event of the death or absence of these conditions, as well as allergy to formulation are excluded. The clinical trial of this formulation will be conducted on 20 cancer patients with Hands and foot syndrome of three medical centers in Tehran and Qom, in a double-blind, placebo-controlled and parallel study. Trial group is combination of phase 1 and 2. The sample is consisted of 40 pairs of hands and feet. Patients are randomly divided into two groups, white and orange; white group receive the placebo gel to their hands and the drug gel to their feet; the orange contrary receive the placebo gel to their feet and the drug gel to their hands for two weeks. The beginning and the fourteenth day of study, the severity of lesions are checked, photographed and questionnaire is completed; syndrome is graded according to data by the National Cancer Institute protocols and changes are investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042116518N2**

Registration date: **2015-08-04, 1394/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-04, 1394/05/13

Registrant information

Name

Mino Afshar

Name of organization / entity

Department of Pharmaceutics, Pharmaceutical Sciences Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 0052

Email address

afsharme@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmaceutical Sciences branch, Islamic Azad University

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the efficacy of a topical dosage form consisting calendula officinalis L., Matricaria recutita L. and Salvia officinalis L extracts in reducing Fluoropyrimidines induced Hand-Foot Syndrome in

cancerous patients

Public title

Investigation of the efficacy of a herbal topical gel in reducing the skin reactions in cancer patients taking chemotherapy drugs

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Taking 5-fluorouracil (5-fu) by injection or orally Capecitabine as an anticancer drug; showing hand-foot syndrome; patient satisfaction; Having cancer. Exclusion criteria: Treatment change and discontinuing 5-fluorouracil (5-fu) and oral Capecitabine administration; Showing no hand-foot syndrome; Patient's death; Lack of cancer; Sensitivity to compounds of formula.

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pharmaceutical Sciences branch, Islamic Azad University

Street address

Pharmaceutical Sciences branch, No. 99, Jasmine alley, Yakchal St., Dr. Shariati St.

City

Tehran

Postal code

193956466

Approval date

2013-10-27, 1392/08/05

Ethics committee reference number

9799

Health conditions studied

1

Description of health condition studied

Hand and Foot Syndrome

ICD-10 code

L27.1

ICD-10 code description

Localized skin eruption due to drugs and medicaments

Primary outcomes

1

Description

severity of HFS symptoms

Timepoint

Beginning of the study , the fourteenth day

Method of measurement

NCI Hand-Foot Syndrome staging version 4.0

Secondary outcomes

1

Description

Skin Sensitivity

Timepoint

From the beginning of the study

Method of measurement

Observational

Intervention groups

1

Description

The topical gel will be administrated to the foot or hand of the patients randomly four times a day for two weeks

Category

Treatment - Drugs

2

Description

The topical placebo will be administrated to the foot or hand of the patients taking the topical drug randomly four times a day for two weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr.Behrooz Gharib

Street address

Shahid Beheshti Hospital, Shahid Beheshti st.

City

Qom

2**Recruitment center****Name of recruitment center**

Naft Hospital

Full name of responsible person

Dr.Behrooz Gharib

Street address

Naft Hospital, Sarhang Sakhaee st., Hafez st.

City

Tehran

3**Recruitment center****Name of recruitment center**

Modarres Hospital

Full name of responsible person

Dr.nematollah rostami

Street address

Modarres Hospital, intersection of Yadegar emam and Saadat abad st.

City

tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Pharmaceutical Sciences branch, Islamic Azad University(a part of Elnaz Karimi's PharmD thesis)

Full name of responsible person

Dr.Sepide Arbabi

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Pharmaceutical Sciences branch, No. 99, Jasmine alley, Yakchal St., Dr. Shariati St.

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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

Pharmaceutical Sciences branch, Islamic Azad University(a part of Elnaz Karimi's PharmD thesis)

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**

Pharmaceutical Sciences branch, Islamic Azad University

Full name of responsible person

Elnaz Karimi

Position

Basic pharmaceutical PhD student

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

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PhD Industrial Pharmacy / faculty

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Position

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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