Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the efficacy of a topical dosage form consisting lawsonia inermis 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 lawsonia inermis 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 one medical center in Tehran , 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, pink and green; pink group receive the placebo gel to their hands and the drug gel to their feet; the green 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: **IRCT2014051017643N1**
Registration date: **2015-08-27, 1394/06/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-27, 1394/06/05

Registrant information

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Recruitment status

Recruitment complete

Funding source
Pharmaceutical Sciences branch, Islamic Azad University

Expected recruitment start date

2014-06-11, 1393/03/21

Expected recruitment end date

2016-01-05, 1394/10/15

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 lawsonia inermis 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 Fluoropyrimidines induced Hand-

Foot Syndrome in cancerous patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Taking 5-fluorouracil (5-fu) by injection or oraly 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

Islamic Azad University Of Pharmaceutical Sciences Branch

Street address

Iakhchal Avenue، Qolhak، Dotor Shariati Avenue، Tehran

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Postal code

19395-6466

Approval date

2013-12-03, 1392/09/12

Ethics committee reference number

11994

Health conditions studied

1

Description of health condition studied

hand-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

Imam Khomeini Hospital of Tehran

Full name of responsible person

Dr.Farhad Shahi

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Institute cancer.Imam Khomeini Hospital Complex،Keshavarz Blvd،Tehran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical Sciences branch, Islamic Azad University(a part of razieh mohajerani's PharmD thesis
Full name of responsible person
Dr.Sepide Arbabi
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Islamic Azad University Of Pharmaceutical Sciences Branch، Iakhchal avenue، Dotor Shariati avenue، Tehran
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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 razieh mohajerani'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

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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