Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Assessment of a topical nano formulation of tretinoin effect in the treatment of Hand-foot syndrome as a side effect of chemotherapeutic agents (Capecitabine, Fluorouracil, Doxorubicin, Docetaxel)

Protocol summary

Summary

The aim of this study is to suggest a proper topical nano formulation of tretinoin to improve Hand-foot syndrome symptoms in patients who received chemotherapy agents like: Capecitabine, Fluorouracil and Docetaxel. 30 cancer patients between 30-80 years old of both sexes with hand-foot syndrome induced by chemotherapy agents are recruited. Written informed consent was achieved from all the patients. Patients are excluded from the investigation in the case of skin infection, sensitivity to our formulation and unwillingness to take apart in the study. This study was designed as a double-blind, placebo-controlled, parallel and randomized clinical trial. Patients were entered in two groups randomly. Group A were patients who applied a thin layer of topical drug on their hands and feet once or twice daily. Group B were patients who received topical placebo with similar regimen. We helped Common Terminology Criteria for Adverse Events (CTCAE) for grading syndrome based on the severity of symptoms. The beginning and the ending day of study, the severity of lesions are checked, photographed and questionnaire is completed and changes are investigated, also each patient was followed every 14 days. The treatment period varied from one to three months based on the patient's response.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707163106N33**
Registration date: **2017-10-10, 1396/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-10, 1396/07/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

by student

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of a topical nano formulation of tretinoin effect in the treatment of Hand-foot syndrome as a side effect of chemotherapeutic agents (Capecitabine, Fluorouracil, Doxorubicin, Docetaxel)

Public title

Assessment of a topical retinoid effect in the treatment

of a cutaneous side effect of chemotherapeutic agents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with hand-foot syndrome; Patients who 30 to 80 years old. Exclusion criteria: Skin infections; Skin cancer; Sensitivity to compounds of formula; Patient dissatisfaction

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Ethics committee of Islamic Azad University Of Pharmaceutical Sciences Branch

Street address

Yakhchal Avenue، Qolhak، Dotor Shariati Avenue، Tehran

City

Tehran

Postal code

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.IAU.PS.REC.1395.10

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 hand-foot syndrome

Timepoint

Beginning of the study, every 14 days, End of the study

Method of measurement

Common Terminology Criteria for Adverse Events

Secondary outcomes

1

Description

Skin Sensitivity

Timepoint

Beginning of the study, every 14 days, End of the study

Method of measurement

Observational

Intervention groups

1

Description

The topical nano-tretinoin will be administrated to hands and feet of patients once or twice daily for 1 to 3 months Based on patients' response.

Category

Treatment - Drugs

2

Description

The topical placebo will be administrated to hands and feet of patients once or twice daily for 1 to 3 months Based on patients' response.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali haspital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar hospital
Full name of responsible person
Street address
City
Tehran

3

Recruitment center
Name of recruitment center
Rasoole Akram hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical Sciences branch, Islamic Azad University(a part of hanieh pourmousavi's PharmD thesis
Full name of responsible person
Dr.Seyd Jalaledin Hosseini Ghoncheh
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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 hanieh pourmousavi'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