Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Study of the Effectiveness of Henna Topical Formulation for the Prevention and Control of Hand-Foot Syndrome Complicated by Capsitibine in Patients with Different Malignancies

Protocol summary

Study aim

To evaluate the efficacy of topical henna formulation in preventing and controlling of local Hand-Foot Syndrome from Capecitabine in patients with cancer.

Design

randomized, superiority, parallel group, double blind, controlled trial with blinded participants and investigator.

Settings and conduct

Cancer patients more than 18 years old who had candidate for capsitibine therapy will enroll. The study will be conducted at department of oncology of the University Hospital Emam Reza, and department of oncology of the University Hospital Omid Mashhad. randomization will be performed after informed consent was obtained. The randomization schedule will be generated by computer. Allocations will be sealed in opaque, numbered envelopes that will be opened after collection of the baseline data. The randomization data will not be available to the investigators. In intervention group Patients receive topical henna formulation twice daily . In placebo group, placebo made by the faculty of pharmacy will be used twice a day by the patient. patients underwent the same evaluations at 1 and 2 months after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Cancer Patients candidate for capsitibine Therapy. Exclusion criteria: Patients that Increased liver enzymes; increased blood creatinine; have fever or severe neutropenia; have Diabetes; autoimmune diseases; taking immunosuppressants and anti-inflammatory drugs excluded

Intervention groups

Intervention group; Patients receive topical alpha ointment twice daily. Placebo group; College-made placebo will be used twice daily by the patient.

Main outcome variables

Evaluation of the side effects and symptomatic improvement after treatment, as measured by the NCI criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181230042179N1**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**
Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name
Sara Rasta
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effectiveness of Henna Topical Formulation for the Prevention and Control of Hand-Foot Syndrome Complicated by Capsitibine in Patients with Different Malignancies

Public title

The Effectiveness of Henna Topical Formulation for the Prevention and Control of Hand-Foot Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cancer Patients Candidate for Capsitibine Therapy

Exclusion criteria:

Increased liver enzymes increased blood creatinine fever, and severe neutropenia that need to be stopped Having Diabetes Use of immunosuppressant and anti-inflammatory drugs Having autoimmune diseases

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, randomly allocate a participant to a treatment group. Prepared a list of all permutations for the sample size, selected one of them and based on arrangement allocated participants to a treatment and control groups with sealed envelope. Participants will be unaware of the type of intervention. Investigator will be unaware of the type of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining informed consent, participants were classified into intervention groups and were not aware of the type of intervention. Researcher and Care provider unaware of the type of intervention when investigate complications and treatment .

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 Sciences

Street address

Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue

City

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Province

Razavi Khorasan

Postal code

1394491388

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.624

Health conditions studied

1

Description of health condition studied

Malignant neoplasm Cancer

ICD-10 code

C00

ICD-10 code description

Malignant neoplasm of lip

2

Description of health condition studied

Malignant neoplasm Cancer

ICD-10 code

C96

ICD-10 code description

Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue

Primary outcomes

1

Description

side effects

Timepoint

Once a week for up to two months after intervention

Method of measurement

NCI Criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: topical henna formulation
Category
Treatment - Drugs

2

Description
Control group: placebo ointment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
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Emam Reza Hospital, Emam Reza square, Ibn Sina Street, Mashhad, Iran.
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2

Recruitment center
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Sponsors / Funding sources

1

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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
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
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Person responsible for updating data

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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
There is no further information
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