

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of discolored Henna cream with placebo in the treatment of cutaneous problems induced by chemotherapy and radiotherapy in cancer patients

Protocol summary

Study aim

The assessment of efficacy of discolored Henna cream in the improvement of skin reactions induced by treatment of cancer

Design

This study was designed as a double-blind, placebo-controlled, parallel and randomized phase 3 clinical trial. 44 patients entered to two groups A or B based on simple randomization method.

Settings and conduct

written informed consent was achieved from involved patients in the Shohadaye Haftetir hospital. It has recommended to all patients in two groups that two times a day wash the skin reaction involved area with mild soap and then use the topical cream as enough. Skin reaction grade were determined by Common Terminology Criteria for Adverse Events (CTCAE). Duration of treatment was two weeks to one month according to skin reaction severity. At the first and end of the study, skin reaction severity was assessed by photo and questionnaire was completed.

Participants/Inclusion and exclusion criteria

Cancer patients from both sex, having cutaneous problems induced by chemotherapy or radiotherapy are involved in this study. Skin cancer and skin infections and sensitivity to herbal products including Henna are exclusion criterias.

Intervention groups

Group A will receive discolored Henna cream on the skin reaction involved area two times a day for two weeks to one month. Group B will receive topical placebo with the same protocol as group A.

Main outcome variables

Severity of skin reaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N7**

Registration date: **2018-02-24, 1396/12/05**

Registration timing: **retrospective**

Last update: **2018-02-24, 1396/12/05**

Update count: **0**

Registration date

2018-02-24, 1396/12/05

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 1889

Email address

r_abrishami@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-11-16, 1396/08/25

Trial completion date

empty

Scientific title

Comparison of the effectiveness of discolored Henna cream with placebo in the treatment of cutaneous problems induced by chemotherapy and radiotherapy in cancer patients

Public title

Efficacy of Henna cream in cutaneous problems induced by cancer therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients having cancer Patients having cutaneous problems induced by chemotherapy or radiotherapy

Exclusion criteria:

Patients having skin cancer Patients having skin infections Patients having allergy to herbal products including Henna

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this investigation, simple randomization method based on random numbers table was used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this investigation participants, investigator, care providers and outcome assessors were blinded that wich patient will receive Henna or placebo topical cream.

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

Street address

#99, Yakhchal Ave., Shariati st.

City

Tehran

Province

Tehran

Postal code

19395_6466

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR.IAU.PS.REC.1395.22

Health conditions studied**1****Description of health condition studied**

Skin reaction induced by radiotherapy, Hand and foot syndrom induced by chemotherapy

ICD-10 code

L58.0, L27

ICD-10 code description

Acute radiodermatitis, Localized skin eruption due to drugs and medicaments

Primary outcomes**1****Description**

Skin reaction severity induced by radiotherapy

Timepoint

Before intervention and at the end of the intervention

Method of measurement

Based on Common Terminology Criteria for Adverse Events and Skindex-16 questionnaire

2**Description**

Hand and foot syndrom severity

Timepoint

Before intervention and at the end of the intervention

Method of measurement

Based on Common Terminology Criteria for Adverse Events and Skindex-16 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients use the discolored Henna cream on the skin reaction involved area two times a day for two weeks to one month according to skin reaction severity

Category

Treatment - Drugs

2

Description

Control group: Patients use the topical placebo on the skin reaction involved area two times a day for two weeks to one month according to skin reaction severity

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Hafta Tir hospital

Full name of responsible person

Atefeh Khodabakhshi

Street address

Shahid Rajaei St., Rey City

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Email

Atefe.c72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Doctor Seyed Jalalodin Hoseini Ghonche

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mehdirj@aol.co.uk

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Atefeh Khodabakhshi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr mehdi rajabi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Atefeh Khodabakhshi
Position
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Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available