

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Henna cream (Lawsonia inermis L) in preventing and reducing the severity of Radiation induced dermatitis in patients with breast cancer

Protocol summary

Study aim

Prevention and reduction of severity of Radiation induced dermatitis in patients with breast cancer

Design

Randomize double blind clinical trial with two parallel control and experimental arm Sample size: 50

Settings and conduct

Patients will be divided into two groups randomly in IMAM HOSEIN hospital. From the beginning of radiotherapy patients will use cream locally in the area under radiation, two times daily, once after treatment and once before bedtime . Patients will be evaluated weekly for complications, and the way of using of the cream. If dermatitis occurs, its grade will be recorded. Radiation dermatitis is graded based on RTOG International Scoring System. Patients, researcher and dermatitis evaluator will be blinded.

Participants/Inclusion and exclusion criteria

Patients with breast cancer who had breast conservative surgery include in this study. Exclusion criteria : Radical mastectomy; Skin involvement; Diabetes; Renal failure; History of hypersensitivity to henna ; Smoking; Skin diseases; History of chest wall irradiation; Concurrent chemotherapy

Intervention groups

Patients with breast cancer who had the indication of radiotherapy are divided into two groups. From the beginning of radiotherapy, natural henna cream is prescribed to experimental group and placebo is prescribed to control group and patients use them in the area under radiation two times daily.

Main outcome variables

Grade of dermatitis; Time of incidence of dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191107045357N1**

Registration date: **2020-05-07, 1399/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-07, 1399/02/18**

Update count: **0**

Registration date

2020-05-07, 1399/02/18

Registrant information

Name

Mansour Lesan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 2610

Email address

mansourlesan@mail.sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Henna cream (Lawsonia inermis L) in

preventing and reducing the severity of Radiation induced dermatitis in patients with breast cancer

Public title

The efficacy of Henna cream in preventing of Radiation induced dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with breast cancer who had breast conservative surgery

Exclusion criteria:

Collagen vascular diseases
Skin diseases
Hypersensitivity to Henna
Smoking
Diabetes mellitus
Chronic renal failure
Concurrent chemotherapy
History of chest wall irradiation
History of severe reaction to topical medication
Inflammatory breast cancer
Radical mastectomy

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, Researcher, Outcome evaluator

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

School of Medicine, Shahid Beheshti University of Medical Sciences; Yaman Street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-14, 1398/02/24

Ethics committee reference number

IR.SBMU.MSP.REC.1398.131

Health conditions studied

1

Description of health condition studied

Radiation induced dermatitis

ICD-10 code

L58.0

ICD-10 code description

Acute radiodermatitis

Primary outcomes

1

Description

Grade of dermatitis

Timepoint

Weekly during radiotherapy

Method of measurement

RTOG Grading Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cream contains 10% henna: From the beginning day of radiotherapy, patients will apply a thin layer of the cream topically to the irradiated areas, twice a day, once after treatment, and once before bedtime.

Category

Treatment - Drugs

2

Description

Control group: Placebo: Cream without pharmaceutical substance: From the beginning day of radiotherapy, patients will apply a thin layer of the cream topically to the irradiated areas, twice a day, once after treatment, and once before bedtime.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Mansour Lesan

Street address

Radiotherapy oncology Department of Imam Hossein hospital; Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 2610

Email

mansourlesan@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

School of Medicine, Shahid Beheshti University of Medical Sciences; Yaman Street

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

info@sbm.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mansour Lesan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Radiotherapy oncology Department of Imam Hossein hospital; Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

009873432610

Email

mansourlesan@sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mansour Lesan

Position

Resident

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Radiotherapy

Street address

Radiotherapy oncology Department of Imam Hossein hospital; Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 2610

Fax**Email**

mansourlesan@mail.sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mansour Lesan

Position

Resident

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Radiotherapy

Street address

Radiotherapy oncology Department of Imam Hossein hospital; Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 2610

Fax

Email

mansourlesan@mail.sbm.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Personal data including demographic data and main outcome results, study protocol, data statistical analysis, Informed consent form , study report

When the data will become available and for how long

Three months after publishing results

To whom data/document is available

Everyone with permission

Under which criteria data/document could be used

For further researches

From where data/document is obtainable

mansour.stan@gmail.com Mansour Lesan

What processes are involved for a request to access data/document

Replying with Email

Comments