Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 HOSSEIN 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 committe 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
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1617763141
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mansourlesan@sbmu.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
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mansour Lesan

Position

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Other areas of specialty/work

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1617763141

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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 mounts 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