Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Formulation of a topical gel containing Lawsonia inermis and Crocin and evaluation its effects on preventing radiation-induced dermatitis in breast cancer patients: A randomized double-blinded placebo-controlled trial.

Protocol summary

Study aim
Determining the effectiveness of gel containing Henna and Crocin extract in the prevention of radiotherapy-induced dermatitis.

Design
This study is a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, which is performed on 50 patients, using RAND function of Excel software for randomization.

Settings and conduct
It is a double-blind randomized controlled clinical trial. Patients receive a uniform product so that neither the physician nor the patient is aware of the contents of the dosage form. Patients who receive radiotherapy will enter the study after obtaining written consent. Patients receive one of the hydrogel products containing Henna and Crocin extract or the basic hydrogel once a day for ten days. Patients are instructed to use only the products mentioned in the study and the necessary warnings about using other products. During and after treatment, every two days, the skin condition undergoing radiotherapy is evaluated for the severity of redness, dryness, itching, burning, and pain (score 0 to 4).

Participants/Inclusion and exclusion criteria
Breast cancer patients aged between 18 and 65 years.

Intervention groups
Daily consumption of Henna extract and Crocin or placebo.

Main outcome variables
The severity of erythema or redness, itching, burning or pain, dry skin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191106045356N20**
Registration date: **2024-08-15, 1403/05/25**
Registration timing: **prospective**

Last update: **2024-08-15, 1403/05/25**
Update count: **0**

Registration date
2024-08-15, 1403/05/25

Registrant information

Name
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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
2024-08-21, 1403/05/31

Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Formulation of a topical gel containing Lawsonia inermis

and Crocin and evaluation its effects on preventing radiation-induced dermatitis in breast cancer patients: A randomized double-blinded placebo-controlled trial.

Public title
Formulation of a topical gel containing Lawsonia inermis and Crocin and evaluation its effects on preventing radiation-induced dermatitis.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients starting radiotherapy Patients aged 18 to 65 years

Exclusion criteria:
Patients with skin diseases Allergy to henna or crocin Severe systemic diseases such as uncontrolled diabetes, epilepsy, immune system defects, etc.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who meet the inclusion criteria are placed in one of two treatment groups with products containing Henna and Crocin (group A) or base hydrogel (group B). Randomization is performed based on the RAND () function of Excel software, and based on this, a table of random numbers is prepared, and patients are placed in groups A or B, respectively, in the rows of this table, and receive the product related to their group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Medicine, Shahid Sadougi University of Medical Sciences, Yazd

Street address
Alem sq.

City
Yazd

Province
Yazd

Postal code
8916978447

Approval date
2024-07-06, 1403/04/16

Ethics committee reference number
IR.SSU.MEDICINE.REC.1403.095

Health conditions studied

1

Description of health condition studied
Dermatitis

ICD-10 code
L30.9

ICD-10 code description
Dermatitis, unspecified

Primary outcomes

1

Description
Severity of erythema or redness

Timepoint
During and after treatment, every ten days, the skin condition undergoing radiotherapy is evaluated for the severity of redness, dryness, itching, burning and pain.

Method of measurement
Scoring erythema or redness using a questionnaire

2

Description
Severity of itching

Timepoint
During and after treatment, every ten days, the skin condition undergoing radiotherapy is evaluated for the severity of redness, dryness, itching, burning and pain.

Method of measurement
Scoring itching using a questionnaire

3

Description
Severity of pain

Timepoint
During and after treatment, every ten days, the skin condition undergoing radiotherapy is evaluated for the severity of redness, dryness, itching, burning and pain.

Method of measurement

Scoring pain using a questionnaire

4

Description
Skin dryness score
Timepoint
During and after treatment, every ten days, the skin condition undergoing radiotherapy is evaluated for the severity of redness, dryness, itching, burning and pain.
Method of measurement
Scoring skin dryness using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It includes 25 patients referred to the radiotherapy center who meet the inclusion criteria, whose order and type of intervention is random based on the RND () function of Excel software. Patients in the intervention group use a hydrogel containing Henna and Crocin extract prepared once a day before radiotherapy in the Faculty of Pharmacy of Shahid Sadoughi University of Medical Sciences in Yazd. After starting treatment, the condition of the lesion is evaluated for loss of epidermis, redness, dryness, itching, burning, and pain (score 0 to 4).
Category
Treatment - Drugs

2

Description
Control group: It includes 25 patients referred to the radiotherapy center who meet the inclusion criteria, whose order and type of intervention is random based on the RAND() function of Excel software. Patients in the control group use a hydrogel base prepared in the Faculty of Pharmacy of Shahid Sadoughi University of Medical Sciences in Yazd, once a day before radiotherapy. After starting treatment, the condition of the lesion is evaluated for loss of epidermis, redness, dryness, itching, burning, and pain (score 0 to 4).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy Center of Shahid Ramezanzadeh Yazd
Full name of responsible person
Dr. Mohammad Reza Lotfaliani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Lotfaliani
Position
Assistant professor
Latest degree

Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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