Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Formulation of a topical gel containing Lawsonia inermis and Aloe vera and evaluation its effects on radiation-induced dermatitis: A randomized double-blinded placebo-controlled trial

Protocol summary

Study aim
Determining the effectiveness of gel containing henna and aloe vera 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 aloe vera 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
Patients with radiotherapy-induced dermatitis between the ages of 18 and 65

Intervention groups
Daily consumption of henna and aloe vera extract 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: **IRCT20191106045356N7**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **prospective**

Last update: **2021-08-01, 1400/05/10**
Update count: **0**

Registration date
2021-08-01, 1400/05/10

Registrant information

Name
Mohsen Zabihi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 35 3820 3865

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-21, 1400/05/30

Expected recruitment end date
2021-11-21, 1400/08/30

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 Aloe vera and evaluation its effects on radiation-

induced dermatitis: A randomized double-blinded placebo-controlled trial

Public title
Formulation of a topical gel containing Lawsonia inermis and Aloe vera and evaluation its effects on radiation-induced dermatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients starting radiotherapy Patients aged 18 to 65 years
Exclusion criteria:
Patients with skin diseases Allergy to henna or aloe vera use the medicine for two consecutive days Severe systemic diseases such as uncontrolled diabetes, epilepsy, immune system defects, etc. Occurrence of local infection and swelling and redness at the site of dermatitis Incidence of dermatitis and the need for medical treatment of the patient
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

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 aloe vera and henna (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 shahid sadoughi university medical
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8916978447
Approval date
2021-05-19, 1400/02/29
Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.106

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 aloe vera extract prepared once a day for ten days 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 for ten days. 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. Mohsen Zabihi

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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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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. Mohsen Zabihi

Position
Assistant professor
Latest degree
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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