

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Country

Iran (Islamic Republic of)

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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.

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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

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