

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Plantago, Marigold and honey (traditional medicine product) with placebo on dermatitis caused by radiotherapy in cancer patients

Protocol summary

Study aim

Determining the effect of traditional medicine product based on barhang compared to placebo on dermatitis caused by radiation therapy in cancer patients.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 84 patients. The rand function of Excel software was used for randomization.

Settings and conduct

On the days when patients go to Vasei Hospital's Radiotherapy Department for treatment, immediately after radiotherapy and 6 hours after radiotherapy, apply a thin layer (one fingertip) of a traditional medicine product or placebo to the dermatitis or radiation therapy site. Skin folds, including axillary, underbreast, groin) are rubbed and examined by a radiotherapist and researcher once a week until the end of radiotherapy at day zero on days 7-14-21... The patient and the examiner do not know the type of medicine. The patient is asked to return three months after the completion of radiotherapy to check for subacute dermatitis (hyperpigmentation.)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study. Mental and intellectual health. Radiotherapy candidate. Residence in Sabzevar and suburbs. Age range: 45-70. Absence of skin disease. No smoking Exclusion criteria: Do not agree to continue participating in the project from the middle of the study. suffer severe complications from radiotherapy. Changing the patient's treatment method from the middle of the treatment process.

Intervention groups

In the intervention group, manufacture ointment containing the extract of larkspur leaves, marshmallow, and honey based on hydrogel, the size of a finger joint, is used on the dermatitis caused by radiation therapy. the control group, hydrogel (placebo) is applied to the area of radiation therapy dermatitis as much as a thumb.

Main outcome variables

itch local pain erythema Dermatitis site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N11**

Registration date: **2022-07-29, 1401/05/07**

Registration timing: **prospective**

Last update: **2022-07-29, 1401/05/07**

Update count: **0**

Registration date

2022-07-29, 1401/05/07

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

a.asadi.mm.1384@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Plantago.Marigold and honey (traditional medicine product) with placebo on dermatitis caused by radiotherapy in cancer patients

Public title

Evaluation of Plantago.Marigold and honey (traditional medicine product) with placebo on dermatitis caused by radiotherapy in cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Mental and intellectual health Radiotherapy candidate Staying in Bezvar and suburbs (all meetings should be held in Bezvar) Age range 45-70 years Absence of underlying chronic disease: dermatology, lupus, active scleroderma, underlying allergy, diabetes, and chronic kidney disease No smoking, drugs and alcohol

Exclusion criteria:

People who have changed their place of residence since the middle of the study Do not agree to continue participating in the project from the middle of the study suffer severe complications from radiotherapy. Changing the patient's treatment method from the middle of the treatment process Failure to use plan drugs have allergies to study drugs

Age

From 45 years old to 75 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

84 cases were selected and were randomly divided into two groups each consisted of 42 subjects. (Simple, individual randomization is done by choosing a sealed envelope).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this way, the patient and the examiner do not know the type of drug used. The drug and the placebo are the same in terms of shape, color and appearance as an ointment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

pardis of Sabzevar University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9618655555

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.MEDSAB.REC.1401.023

Health conditions studied

1

Description of health condition studied

radiation therapy-induced dermatitis

ICD-10 code

L58.9

ICD-10 code description

Radiodermatitis, unspecified

Primary outcomes

1

Description

dermatitis

Timepoint

Day 0 (day of starting radiation therapy and start of intervention) and days 7-14-21 after the treatment and one month after the end of the treatment to check acute dermatitis and 3 months after the end of treatment to check sub-acute dermatitis

Method of measurement

CTCAE v5.0

Secondary outcomes

1

Description

itching

Timepoint

(From start of intervention) to day 7-21-28 (from the start of radiotherapy once a week)

Method of measurement

self expression

2

Description

Erythema

Timepoint

(From start of intervention) to day 7-21-28 (from the start of radiotherapy once a week)

Method of measurement

view

Intervention groups

1

Description

Intervention group: Intervention group: The medicine of the intervention group is hydrogel, which includes marigold, marshmallow, and honey. This topical skin hydrogel will be made by a pharmacist under the supervision of the Mashhad Faculty of Pharmacy. On the days when patients come for treatment (radiotherapy), immediately after radiotherapy and 6 hours after radiotherapy A thin layer (one finger) of the traditional medicine product is applied to the dermatitis or radiation therapy site (skin folds including axillary, underbreast, groin).

Category

Treatment - Other

2

Description

Control group: The medicine of the control group, the ointment, contains hydrogel. This topical hydrogel will be made by a pharmacist under the supervision of the Mashhad Faculty of Pharmacy. The patients of the control group, on the days they come for treatment (radiotherapy), apply a thin layer (a thin layer) immediately after radiotherapy and 6 hours after radiotherapy. They apply the hydrogel to the place of dermatitis or radiation therapy (skin folds including axillary, underbreast, groin).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Department of Vasei Hospital affiliated to Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Street address

pardis of university

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mohammad Saghi

Street address

Enghelab7. pelak4

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable