Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9618655555
Phone
+98 51 4422 9081
Email
a.asadi.mm.1384@gmail.com

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
City
Sabzevar
Province
Razavi Khorasan
Postal code
961855555
Phone
+98 51 4466 9081
Email
a.asadi.mm.1384@gmail.com
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
Street address
Enghelab
City

Sabzevar

Province
Razavi Khorasan

Postal code
9618655555

Phone
+98 51 4422 9081

Email
a.asadi.mm.1384@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Atefah Asadi

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Enghelab

City
Sabzevar

Province
Razavi Khorasan

Postal code
9618655555

Phone
+98 51 4422 9081

Email
a.asadi.mm.1384@gmail.com

Person responsible for updating data

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

Street address
Enghelab

City
Sabzevar

Province
Razavi Khorasan

Postal code
9618655555

Phone
+98 51 4422 9081

Email
a.asadi.mm.1384@gmail.com

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