

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparing the effectiveness of Alpha and hydrocortisone %1 ointment to prevent severe skin complications among patients with breast cancer

Protocol summary

Summary

The present study aims to compare the effectiveness of Alpha and hydrocortisone %1 ointment to prevent severe skin complications among patients with breast cancer. It is a double blind clinical study. 90 patients with advanced breast cancer under radiation therapy in Imam Reza hospital of Kermanshah city were selected randomly and divided into experiment groups. The first group used a thin layer of alpha ointment twice a day (a centimeter of ointment for 10*10 cm) on radiated area. The ointment is applied 2 hours after radiation and also 8 hours later. Notice that the area is cleaned using soap before radiation. The second group used hydrocortisone %1 ointment with the same dose and application. Then, variables of severe dermatitis resulting from radiation, pain, irritation and itch were investigated by physicians and through asking the patients at the beginning of the study and once a week to the end of the study in both groups. Inclusion criteria: written consent by patients; being treated by final mastectomy; at least three weeks after the last session of chemotherapy; having no burn, cut, infection and skin problems on radiation area. Exclusion criteria: having a history on collagen diseases, cases of diabetes through treatment; using systematic steroids; intolerance of radiation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052114333N34**

Registration date: **2015-07-20, 1394/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-20, 1394/04/29

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Alpha and hydrocortisone %1 ointment to prevent severe skin complications among patients with breast cancer

Public title

Effectiveness of Alpha and hydrocortisone %1 ointment to prevent severe skin complications among patients with breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: written consent by patients; being

treated by final mastectomy; at least three weeks after the last session of chemotherapy; having no burn, cut, infection and skin problems on radiation area. Exclusion criteria: having a history on collagen diseases, cases of diabetes through treatment; using systematic steroids; intolerance of radiation.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomly using sealed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

kums.rec.1394.5

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

itching

Timepoint

Beginning of study, once a week and end of the study(6 to 7 weeks after beginning)

Method of measurement

Asking the patients

2

Description

irritation

Timepoint

Beginning of study, once a week and end of the study(6 to 7 weeks after beginning)

Method of measurement

Asking the patients

3

Description

Pain levels

Timepoint

Beginning of study, once a week and end of the study(6 to 7 weeks after beginning)

Method of measurement

Asking from the patients

4

Description

Severe skin complications

Timepoint

Beginning of study, once a week and end of the study(6 to 7 weeks after beginning)

Method of measurement

Based on observations and physician examination, RTOG according to the criterion

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the first group used a thin layer of alpha ointment produced by Alpha Tose company twice a day (a centimeter of ointment for 10*10 cm) on radiated area. The ointment is applied 2 hours after radiation and also 8 hours later he first application. Notice that the area is cleaned using soap before radiation.

Category

Treatment - Drugs

2

Description

The second group used a thin layer of hydrocortisone %1 ointment produced by Sina company twice a day (a centimeter of ointment for 10*10 cm) on radiated area. The ointment is applied 2 hours after radiation and also 8 hours later the first application. Notice that the area is cleaned using soap before radiation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza Hospital

Full name of responsible person

Ali Goli

Street address

Emamreza hospital, Parastar boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Ahmad Khoshay

Position

Msc. of Surgical Internal Nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery, First of Dolatabad Boulevard, Eisar Square

City

Kermanshah

Postal code

Phone

+98 83 3827 9304

Fax

Email

Akhoshay@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty