Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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 Boulvard,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