The efficacy and safety of topical Alpha ointment (containing natural Henna) compared to topical hydrocortisone 1% on healing of radiation-induced dermatitis in breast cancer patients

Protocol summary

Summary
This two-arm randomized clinical study aimed to compare the efficacy of topical Alpha ointment with topical hydrocortisone 1% ointment on healing of radiation-induced dermatitis in breast cancer patients. Between July 2011 and December 2012, 60 eligible patients were randomly (using random number tables) assigned to received either topical Alpha ointment (study group, n = 30), or topical hydrocortisone 1% ointment (control group, n = 30) immediately after completing postmastectomy chest wall radiotherapy with a median dose of 45-50 Gy. In addition, all patients in both groups were recommended to take daily chest wall simple washing with mild soap. Dermatitis grade was determined according to the Common Terminology Criteria for Adverse Events version 4.0. The dermatitis area (cm2) was measured independently by 2 physicians in each exam till 4 weeks after starting intervention. The patients’ complaints including skin burning, pain, pruritus and amount of skin discharge change will be scored from 0 to 3 in our data sheet in each exam (subjective scores will be defined as 0: no complaint, 1: mild, 2: moderate and 3: severe complaint). The primary and the secondary endpoints of the study are the rate of healing and the safety of Alpha ointment in radiation dermatitis.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201206099979N1
Registration date: 2013-03-09, 1391/12/19
Registration timing: retrospective

Last update: 0
Registration date: 2013-03-09, 1391/12/19

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source Shiraz University of Medical Sciences

Expected recruitment start date 2012-01-01, 1390/10/11
Expected recruitment end date 2012-07-01, 1391/04/11
Actual recruitment start date empty
Actual recruitment end date empty
Trial completion date empty

Scientific title
The efficacy and safety of topical Alpha ointment (containing natural Henna) compared to topical hydrocortisone 1% on healing of radiation-induced dermatitis in breast cancer patients

Public title
Alpha ointment (Henna) and hydrocortisone in radiation-induced dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Eligible patients had to have newly pathologically proven diagnosed locally advanced breast cancer treated with modified radical mastectomy followed by sequential adjuvant chemotherapy and chest wall radiotherapy (45-50.4 Gy), and developed grade 2 and/or 3 radiation-induced dermatitis. Exclusion criteria: 1. Any history of collagen vascular diseases, or diabetes mellitus, 2. Taking any drugs interacting wound healing process, like systemic steroids, 3. Previous history of
chest wall radiotherapy and 4. Concurrent use of chemotherapy. All patients had to sign a consent form approved by the local research ethics committee before participating in the study.

Age
From 20 years old to 90 years old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1
Registry name
The Australian New Zealand Clinical Trials Registry
Secondary trial Id
ACTRN12612000837820
Registration date
2012-09-08, 1391/06/18

Ethics committees

1
Ethics committee
Name of ethics committee
Medical Research Ethic Committee of Shiraz University of Medical Sciences
Street address
Medical Research Ethic Committee of Shiraz University of Medical Sciences
City
Shiraz
Postal code
7193636111

Approval date
2011-07-05, 1390/04/14

Ethics committee reference number
CT-P-90-2764

Health conditions studied

1
Description of health condition studied
severity of radiation - induced skin reaction

ICD-10 code
L58.0, L58

ICD-10 code description
Radiodermatitis

Primary outcomes

1
Description
severity of radiation-induced skin reaction

Timepoint
Just before intervention and then weekly for 4 weeks

Method of measurement
Dermatitis area (cm2) were measured (by grid paper) and estimated

Secondary outcomes
empty

Intervention groups

1
Description
Study group: Just before starting intervention, the patients were examined carefully; and patients’ data including age, stage, area of dermatitis grade 2 and 3, and severity of patients’ complaints were recorded. The area of dermatitis grade 2 and 3, and severity of patients’ complaints then was evaluated and registered weekly. In control group, topical Alpha ointment (produced by Alpha Development Company) was used with daily washing the chest wall area. Detailed instructions on topical Alpha were given to each patient as follows. Patients were instructed to apply a thin (1 millimeter) layer of the topical Alpha two times a day over chest wall field and to wash daily dermatitis area with water and mild soap. Treatment was started from the day of the last session of radiotherapy and continuing every day for 3 weeks. Each patient was examined weekly for 4 weeks.

Category
Treatment - Drugs

2
Description
Control group Just before starting intervention, the patients were examined carefully; and patients’ data
including age, stage, area of dermatitis grade 2 and 3, and severity of patients’ complaints were recorded. The area of dermatitis grade 2 and 3, and severity of patients’ complaints then was evaluated and registered weekly. In control group, topical hydrocortisone 1% cream was used with daily washing the chest wall area. Detailed instructions on topical hydrocortisone 1% were given to each patient as follows. Patients were instructed to apply a thin (1 millimeter) layer of the topical hydrocortisone 1% two times a day over chest wall field and to wash daily dermatitis area with water and mild soap. Treatment was started from the day of the last session of radiotherapy and continuing every day for 3 weeks. Each patient was examined weekly for 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Department of Radiation Oncology
Full name of responsible person
Mohammad Mohammadianpanah
Street address
Department of Radiation Oncology, Cancer Research Center, Namazi Hospital, Shiraz University of Medical Sciences, Shiraz 71936, Iran,
City
Shiraz

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Gholam Reza Hatam
Street address
Zand Street
City
Shiraz
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, Shiraz 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
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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