Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

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:
Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name
Mohammad Mohammadianpanah
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1612 5168
Email address
mohpanah@sums.ac.ir

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

ثبت کارآزمائي هاي باليني استراليا و نيوزيلند

Secondary trial Id

ACTRN12612000837820

Registration date

empty

2

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mohammadianpanah

Position

Associate Professor of Radiation Oncology

Other areas of specialty/work

Street address

Namazi Hospital

City

Shiraz

Postal code

Phone

+98 71 1612 5168

Fax

+98 71 1647 4320

Email

mohpanah@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mohammadianpanah

Position

Associate Professor of Radiation Oncology

Other areas of specialty/work

Street address

Namazi Hospital

City

Shiraz

Postal code

Phone

+98 71 1612 5168

Fax

+98 71 1647 4320

Email

mohpanah@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mohammadianpanah

Position

Academic member

Other areas of specialty/work

Street address

Namazi Hospital

City

Shiraz

Postal code

7193613511

Phone

+98 71 1612 5168

Fax

+98 71 1647 4320

Email

mohpanah@gmail.com

Web page address

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