Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of nano-curcumin on radiotherapy-induced skin reaction in breast cancer patients: a randomized, triple-blind, placebo-controlled trial

Protocol summary

Study aim

Determination of radiation-induced skin burns of breast cancer patients in two groups receiving nano-corcumin capsules and control

Design

Two arm randomised trial, triple blinded, Phase 3 on 42 patients.

Settings and conduct

The present study will be done on patients undergoing breast cancer radiotherapy referred to the Yasrebi Hospital,Kashan, Iran in 2020-2021. The patients will be treated with a standard radiotherapy regimen of one fraction per day, 5 days a week, 25 treatment fractions(5 weeks), radiation dose per fraction of 200 cGy and a total radiation dose of 5000 cGy. The patients will take Nano-curcumin capsules in order to reduce radiation-induced skin reactions. 42 patients with easy sampling were entered and divided by a mixture of 2 and 4 randomized blocks into two groups of control and treated with nano-curcumin.The patient will be unaware of the type of medication prescribed.The control group will only receive a standard radiotherapy regimen and the treatment group will receive a standard radiotherapy regimen plus Nano-curcumin.The patients will receive nano-curcumin from the first fraction of radiotherapy and continue until the end of the treatment.Finally,skin evaluation of patients will be done weekly by a radiation oncologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Breast cancer patients who will undergo radiotherapy. Exclusion criteria: Patients with previous breast cancer radiotherapy; Bilateral breast cancer; Concurrent chemotherapy; Tacking anticoagulants medications; Skin conditions or sensitivity to formulations; treated with an anti-epidermal growth factor receptor or partially irradiated; with diagnosis of inflammatory breast cancer; breast reconstruction

Intervention groups

Intervention with administration of nano-curcumin capsules and control without prescription

Main outcome variables

The amount of radiation induced skin reaction

General information

Reason for update

End the trial Record the date of onset of the disease Record the end date of the patient Record the end date of the trial Convert Nano-curcumin to nano-curcumin Correct the English title of the trial Extending the age range of the studied patients from 70 to 80 years

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047427N1**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**
Update count: **1**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name
Tamara Talakesh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8831 5138
Email address
tamara.talakesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

2020-09-06, 1399/06/16

Actual recruitment end date

2020-12-13, 1399/09/23

Trial completion date

2021-01-24, 1399/11/05

Scientific title

Effect of nano-curcumin on radiotherapy-induced skin reaction in breast cancer patients: a randomized, triple-blind, placebo-controlled trial

Public title

Effect of nano-curcumin on radiotherapy-induced skin reaction in breast cancer patients: a randomized, triple-blind, placebo-controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer patients who will undergo radiotherapy.

Exclusion criteria:

Patients whose breast region have previously been irradiated. Patients with bilateral breast cancer. Patients receiving concurrent chemotherapy and radiotherapy Patients taking anticoagulants such as warfarin (Coumadin) or heparin Patients with skin conditions (such as bleeding, ulcers or incurable wounds) or sensitivity to formulations Patients treated by anti-epidermal growth factor (EGRF) Patients undergoing minor radiation to the breast area Patients with special skin allergies Patients with diagnosis of inflammatory breast cancer and reconstructive treatment

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization 42 patients referred to the Yasrebi radiotherapy centre will enter the study with easy sampling. These individuals are then divided into two groups of control and treated with nano-curcumin using a mixture of 2 and 4 randomized blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding is done in such a way that patients, physicians, and data analysts are unaware of the type of intervention involved, and only the person who assigns the medication and control to patients is aware of the type of treatment.Patients are blinded by taking placebo.The treating physician treats and cares for patients without knowing the type of medication.The clinician who is responsible for evaluating the outcome reports her observations without knowing which patient has taken the placebo and which patient is taking the main medication.The data analyzer also receives data as A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research,Faculty of Nursing & Midwifery, Faculty of Health & Faculty of Paramedi

Street address

5th of Qotb –e Ravandi Blvd., Pezeshk Blvd., faculty of Nursing and Midwifery

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.001

Health conditions studied

1

Description of health condition studied

Radiation induced skin reactions

ICD-10 code

L58.0

ICD-10 code description

A radiation burn is damage to the skin or other biological tissue caused by exposure to radiation. The radiation types of greatest concern are thermal radiation, radio frequency energy, ultraviolet light and ionizing radiation.

Primary outcomes

1

Description

skin burn grade

Timepoint
Determination of skin reactionس at the beginning of the study (before the intervention), 7, 14, 21, 28 and 35 days after the start of nano-curcumin capsule consumption
Method of measurement
Determination of skin reaction (skin burn grade) according to the criteria of the Radiotherapy-Oncology group by a radiation oncologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: nano-curcumin Capsule (Exir Nano Sina Co.) as an 80mg gelatin capsule, one capsule per day after breakfast, from the first radiotherapy fraction to the last radiation therapy fraction.
Category
Prevention

2

Description
Control group: No medication
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy center, Yasrebi Hospital
Full name of responsible person
Mostafa Sarvizadeh
Street address
Parastar Blvd., Ghotb Ravandi Blvd.
City
Kashan
Province
Isfehan
Postal code
8715973454
Phone
+98 31 5558 5000
Fax
+98 31 5562 1530
Email
info@yasrebihospital.ir
Web page address
http://yasrebihospital.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
Street address
Pezeshk Blv., Qotb–e Ravandi Blvd.
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 2999
Fax
+98 31 5557 5057
Email
research@kaums.ac.ir
Web page address
http://research.kaums.ac.ir/
Grant name
Grant code / Reference number
98227
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Tamara Talakesh
Position
M.Sc. student
Latest degree
Master
Other areas of specialty/work
Medical Physics
Street address
No.16, 15th Ave., Mirzay -e- shirazi St.
City
Tehran
Province
Tehran
Postal code

1586633813

Phone
+98 21 8831 5138

Fax

Email
tamara.talakesh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Bagher Farhood

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Physics

Street address
Pezeshk Blvd., Ghotb Ravandi Blvd.

City
Kashan

Province
Isfehan

Postal code
8715981151

Phone
+98 31 5554 8883

Fax
+98 31 5554 8883

Email
bffarhood@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Tamara Talakesh

Position
M.Sc. student

Latest degree
Master

Other areas of specialty/work
Medical Physics

Street address
No.16, 15th Ave., Mirzay -e- shirazi St.

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Tehran

Province
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Postal code
1586633813

Phone
+98 21 8831 5138

Email
tamara.talakesh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The documents include tables of the recovery process of patients who have used the medication. All potential data can be shared after blinding.

When the data will become available and for how long
Start of access period: 6 months after the publication of the results.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Any kind of analysis and mechanism to improve and increase the well-being of patients and the development of science in accordance with ethical standards and protect the rights of researchers in this trial and not to distort the data.

From where data/document is obtainable
Department of Medical Physics and Radiology, Faculty of Paramedical Sciences, Kashan University of Medical Sciences, Kashan, Iran Dr. Bagher Farhood, Email: bffarhood@gmail.com Tamara Talakesh, Email: tamara.talakesh@gmail.com

What processes are involved for a request to access data/document
The request must be sent in writing or by e-mail, and after review by the research team and the observance of ethical and legal conditions, it is agreed to send the data.

Comments