Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study the radioprotective effects of oral atorvastatin on side effects and effectiveness of radiotherapy in patients with breast cancer: A randomized clinical trial, evaluate of oxidative stress biomarkers and quality of life

Protocol summary

Study aim

Determination of the Effect of Oral Atorvastatin on the Complications and Effect of Radiation Therapy in Patients with Breast Cancer

Design

A simple randomized clinical trial with a placebo-controlled, double-blind, control group with a sample size of 90

Settings and conduct

The researcher identifies eligible patients in the radiotherapy department of Imam Khomeini hospital in sari. First, patients will receive written consent to enter the research.They will then be selected as a research sample. Professor of supervisor, drugs will divide the numbers into two groups using a random number table. 1- An intervention group containing 40 mg per day of atorvastatin and 2. Control group containing placebo So the researchers and patients will be blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with breast cancer Based on bra / breast size ≤85 Not having sensitivity to atorvastatin exclusion criteria: Taking anti-inflammatory drugs Taking antidepressants drugs cardiovascular patients history of systemic lupus and scleroderma.

Intervention groups

Both intervention and control groups will receive radiotherapy with a standard two-way tangent technique 5000CG / 25F photon. The intervention group will receive 40 mg atorvastatin and the control group will receive the placebo.

Main outcome variables

Evaluation of skin dermatitis and assessment of the quality of life of patients with breast cancer undergoing radiotherapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181005041239N1**
Registration date: **2019-02-01, 1397/11/12**
Registration timing: **prospective**

Last update: **2019-02-01, 1397/11/12**
Update count: **0**

Registration date

2019-02-01, 1397/11/12

Registrant information

Name

Mahmonir Danesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7343

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study the radioprotective effects of oral atorvastatin on side effects and effectiveness of radiotherapy in patients with breast cancer: A randomized clinical trial, evaluate of oxidative stress biomarkers and quality of life

Public title
The effect of radiation protection of oral atorvastatin in patients with breast cancer receiving radiotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Have the ability to read and write in farsi or be able to communicate if they are illiterate. Women aged 18 and over Women with breast cancer who receive radiation dosage during treatment with the standard technique of bilateral tangent 5000CG / 25F Photon. Awareness of the person, time and place The possibility of making direct telephone calls to a patient or an active member of his family (to follow the samples) Based on bra / breast size ≤85 Women without known diseases and under medical treatmentSuch as diabetes, thyroid disorders, known liver disease, immune system weakness, rhabdomyolysis and cardiovascular disease, hyperlipidemia, depression and anxiety and taking statins with a doctor's order. Not using a psychologist or psychiatrist's counsel at the time of the study or at least a month before the study begins.

Exclusion criteria:
Allergy to atorvastatin Taking anti-inflammatory drugs Addicted to alcohol, cigarettes and drugs

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to study. The presenter will place the envelopes containing the medication or placebo on the order of one to ninety by using random numbers. For each research sample, a research folder with the same code number or placebo code that contains all the tools for patient information will be formed. The drug envelope or placebo will be given to the research samples on the first day of the research entry. The date of the start of medication use will be noted on the envelope of medicines by label. The researcher will also remind them of the timely use of the drug by contacting the patient's telephone number. Taking a medication or placebo two weeks before the date of the first radiotherapy session will be one night.

Blinding (investigator's opinion)
Double blinded

Blinding description
The supervisor will place the envelopes containing the medication or placebo on the order of 1 to 90 with random numbers. In this way, the researcher, the subjects, and the doctors and statisticians will be blind to the intervention and control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Moalem Ave, Moalem Squer

City
Sari

Province
Mazandaran

Postal code
4817844718

Approval date
2018-09-29, 1397/07/07

Ethics committee reference number
IR.MAZUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied
Breast cancer & Radiotherapy

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Evaluation of skin inflammation

Timepoint
Patients will be examined for the first time before the intervention and then the end of each week until two

weeks after the completion of radiotherapy, this examination will be done.

Method of measurement

radiation therapy oncology group (RTOG)

2

Description

Evaluation of the degree of itching,

Timepoint

Patients will be examined for the first time before the intervention and then the end of each week until two weeks after the completion of radiotherapy, this examination will be done.

Method of measurement

visual scale analog

3

Description

Assessing the amount of pain

Timepoint

Patients will be examined for the first time before the intervention and then the end of each week until two weeks after the completion of radiotherapy, this examination will be done.

Method of measurement

visual scale analog

4

Description

Evaluation of C reactive proteains

Timepoint

The CRP marker is measured once before the intervention and once after the completion of radiotherapy

Method of measurement

This marker is quantitatively quantified by assessing the blood serum of patients.

5

Description

Evaluation of oxidative stress in blood

Timepoint

Once in the first intervention and once after the completion of radiotherapy, the patient's serum is measured.

Method of measurement

This marker is quantitatively quantified by assessing the blood serum of patients.

6

Description

Evaluation of burning rate

Timepoint

Patients will be examined for the first time before the intervention and then the end of each week until two weeks after the completion of radiotherapy, this examination will be done.

Method of measurement

visual scale analog

7

Description

Evaluate the amount of edema

Timepoint

Patients will be examined for the first time before the intervention and then the end of each week until two weeks after the completion of radiotherapy, this examination will be done.

Method of measurement

Self-declaration of patients and clinical examination

Secondary outcomes

1

Description

quality of life

Timepoint

Before intervention radiotherapy and after the completion of radiotherapy

Method of measurement

1. A questionnaire for quality of life for cancer patients EORTC QLQ – BR23 . 2. The quality of life of cancer patients belonging to the European Cancer Research Organization and the specific breast cancer questionnaire EORTC QLQ C-30.

Intervention groups

1

Description

The intervention group: Women with breast cancer will receive radiotherapy with the standard technique of two-sided 5000CG / 25F photon tangent in the radiation center at Imam Khomeini hospital in sari. Patients are receiving the film coated tablet atorvastatin 40 mg without line per daily. Tablets manufactured by sobhan darou Pharmaceutical Company. Beginning of tablet ingestion is two weeks before radiotherapy and with the completion of radiotherapy, the tablets are consumed.

Category

Treatment - Drugs

2

Description

Control group: Women with breast cancer will receive radiotherapy with the standard technique of two-sided 5000CG / 25F photon tangent in the radiation center at Imam Khomeini hospital in sari. Patients will receive one placebo per night. Beginning of placebo ingestion is two weeks before radiotherapy and with the completion of radiotherapy, the tablets are consumed. The placebo has been produced at sari school of pharmacy under the supervision of the supervisor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Mahmonir Danesh
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Seyed Jalal Hosseinimehr
Position
Ph.D Professor Department of Radiopharmacy Faculty of Pharmacy
Latest degree
Specialist
Other areas of specialty/work
Radiobiology and Radio safety
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
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Mahmonir Danesh
Position
Resident
Latest degree
Master
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Midwifery
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18 km of Khazarabad road, 18 km of Khazarabad road Complex of Payabar Azam, University of Medical Sciences, Faculty of Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"No more information".
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available