Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Evaluation of the effect of atorvastatin in the prevention of gastrointestinal toxicity in patients undergoing pelvic radiotherapy

Protocol summary

Study aim
Determination of the effect of atorvastatin in the prevention of gastrointestinal toxicity in patients undergoing pelvic radiotherapy

Design
Non-randomized, Double-blinding clinical trial, with the parallel groups, Phase 3 on 64 patients

Settings and conduct
In this non-randomized double-blind clinical trial study, 64 patients with pelvic radiotherapy indications referred to Seyyed Al-Shohada hospital in Isfahan will be included and divided into 2 groups. One group will receive atorvastatin and the other group will receive a placebo. Then the degree of gastrointestinal toxicity of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include ح elvic radiotherapy indication due to gynecological, urological and lower gastrointestinal cancers, at least 18 years old, the total pelvic dose of patients during radiotherapy should be between 45-50 Gy, acceptable renal function and GFR> 60, and satisfaction to participate in the study. Exclusion criteria include having a history of pelvic radiotherapy, having diabetes due to the possibility of intestinal disorders, having an active liver or muscle disease, having contraindications to the use of statins, having a serious physical or mental problem that prevents the completion of the course of treatment, evidence of metastasis (having a performance status score greater than 70), taking cytochrome P450 3A4 inhibitors. and withdrawal from continuing to study.

Intervention groups
Intervention group: Patients are treated with atorvastatin at a dose of 40 mg daily from the beginning of radiotherapy to 3 months after treatment. Control group; Patients are treated with the placebo at a dose of 40 mg daily from the beginning of radiotherapy to 3 months after treatment.

Main outcome variables
Gastrointestinal toxicity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N36**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date
2021-08-06, 1400/05/15

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-22, 1400/05/31

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Evaluation of the effect of atorvastatin in the prevention of gastrointestinal toxicity in patients undergoing pelvic radiotherapy

Public title
The effect of atorvastatin in the prevention of gastrointestinal toxicity in patients undergoing pelvic radiotherapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pelvic radiotherapy indication due to gynecological, urological and lower gastrointestinal cancers. At least 18 years old. The total pelvic dose of patients during radiotherapy should be between 45-50 Gy. Acceptable renal function and GFR> 60 Satisfaction to participate in the study

Exclusion criteria:
Having a history of pelvic radiotherapy. Having diabetes due to the possibility of intestinal disorders Having an active liver or muscle disease Having the contraindications to the use of statins Having a serious physical or mental problem that prevents the completion of the course of treatment Evidence of metastasis (having a performance status score greater than 70) Taking cytochrome P450 3A4 inhibitors Unwillingness to participate in the study

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, two drugs, atorvastatin and placebo, are prepared by the pharmacist in the same shape, color. Then these are placed in coded packages and provided to the researcher, who prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2021-03-02, 1399/12/12

Ethics committee reference number
IR.MUI.MED.REC.1399.1146

Health conditions studied

1

Description of health condition studied
Gynecological cancer

ICD-10 code
C57.9

ICD-10 code description
Malignant neoplasm of female genital organ, unspecified

2

Description of health condition studied
Urological Cancer

ICD-10 code
C67.9

ICD-10 code description
Malignant neoplasm of bladder, unspecified

Primary outcomes

1

Description
Gastrointestinal toxicity

Timepoint
Before the intervention, during the intervention, immediately after the intervention, three months after the intervention

Method of measurement
Inflammatory Bowel Disease questionnaire-bowel(IBDQ-B)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are treated with atorvastatin at a dose of 40 mg daily from the beginning of radiotherapy to 3 months after treatment.
Category
Treatment - Drugs

2

Description
Control group: Patients are treated with placebo at a dose of 40 mg daily from the beginning of radiotherapy to 3 months after treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyyed Al-Shohada Hospital
Full name of responsible person
Simin Hemati
Street address
Nahr Farshadi Alley, Khayyam Street
City
Isfahan
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8174673461
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+98 31 3235 0213
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Hematti@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Simin Hemati
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Radiotherapy
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Radiotherapy Department, Seyed Al-Shohada Hospital,Khayyam Street.
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Person responsible for scientific inquiries

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Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Simin Hemati
Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Neda Mohammadi

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available