# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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**
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**Postal code**
8174673461
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**Email**
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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+98 31 3668 8597
**Email**
dean@med.mui.ac.ir
**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
**Street address**
Radiotherapy Department, Seyed Al-Shohada Hospital,Khayyam Street.
**City**
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**Postal code**
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## Person responsible for scientific 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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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Neda Mohammadi

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

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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