

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the preoperative radiotherapy with postoperative radiotherapy in patients with soft tissue sarcoma of the extremity referred to Firoozgar Hospital during 2017 to 2019

Protocol summary

Study aim

The comparison of the preoperative radiotherapy with postoperative radiotherapy in patients with soft tissue sarcoma of the extremity referred to Firoozgar Hospital during 2017 to 2019

Design

A non-randomized, unblinded, phase II clinical trial with a parallel group design of 80 patients, enrolled between July 2017 and September 2019.

Settings and conduct

In this randomized clinical trial, patients with proven diagnosis of localized soft tissue sarcoma of the extremity referring to orthopedic clinic of Firoozgar hospital in Tehran during 2017-2019 will be enrolled. Patients will be randomly divided into two equal groups (n = 40 in each group): 1- Preoperative Radiotherapy: Patients first will receive radiation therapy at a mean dose of 50 Gy between 4 and 6 weeks and then undergo limb preservation surgery. 2- Postoperative Radiotherapy: Patients first will undergo limb preservation surgery by an orthopedic surgeon and receive radiation therapy with 60-66 Gy after surgical wound healing. All patients will be evaluated during 1st, 6th and 12th months after treatment using a questionnaire for complications and limb function.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with pathologically confirmed localized soft tissue sarcoma of the extremity; age $\geq$ 18 years; performance status $<$ 2; Signing the informed consent form. Exclusion criteria include distant metastasis; pregnancy; history of connective tissue diseases

Intervention groups

1- Preoperative Radiotherapy Group: Patients first will receive radiation therapy at a dose of 50 Gy between 4 and 6 weeks and then undergo limb preservation surgery. 2- Postoperative Radiotherapy Group: Patients

first will undergo limb preservation surgery by an orthopedic surgeon and receive radiation therapy with 60-66 Gy after surgical wound healing.

Main outcome variables

survival, recurrence and complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180919041070N3**

Registration date: **2020-01-12, 1398/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

Registration date

2020-01-12, 1398/10/22

Registrant information

Name

Pedram Fadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5522 8584

Email address

fadavi.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-18, 1398/09/27

Expected recruitment end date

2020-03-17, 1398/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the preoperative radiotherapy with postoperative radiotherapy in patients with soft tissue sarcoma of the extremity referred to Firoozgar Hospital during 2017 to 2019

Public title

Radiotherapy of soft tissue sarcoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pathologically confirmed localized soft tissue sarcoma of the extremity Age $\geq$ 18 years Performance status $<$ 2

Exclusion criteria:

Distant metastasis Pregnancy History of connective tissue diseases

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Medical School of Iran
University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.IUMS.FMD.REC.1398.446

Health conditions studied**1****Description of health condition studied**

Malignant neoplasm of connective and soft tissue

ICD-10 code

C49.9

ICD-10 code description

Malignant neoplasm of connective and soft tissue,
unspecified

Primary outcomes**1****Description**

Survival

Timepoint

12 months after treatment

Method of measurement

visiting the patient

2**Description**

Recurrence

Timepoint

1, 6, and 12 months after treatment

Method of measurement

Taking history and physical exam

3**Description**

Limb function

Timepoint

1, 6, and 12 months after treatment

Method of measurement

physical exam

Secondary outcomes**1****Description**

Complications

Timepoint

1, 6, and 12 months after treatment

Method of measurement

Physical exam

Intervention groups

1

Description

Intervention group 1; Preoperative Radiotherapy:
Patients first will receive radiation therapy at a mean dose of 50 Gy between 4 and 6 weeks and then undergo limb preservation surgery.

Category

Treatment - Other

2

Description

Intervention group 2; Postoperative Radiotherapy:
Patients first will undergo limb preservation surgery by an orthopedic surgeon and receive radiation therapy with 60-66 Gy after surgical wound healing.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Pedram Fadavi

Street address

Firoozgar Hospital, Beh Afarin St, Valiasr Sq., District 6

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malekoti

Street address

Fifth Floor, Central Headquarters, Iran University of Medical Sciences, Hemet Highway Between Chamran and Sheikh Fazlollah

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Email

research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hamideh Mahmoudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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Position
Assistant professor

Latest degree
Specialist

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Radiotherapy

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Person responsible for updating data

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Other areas of specialty/work
Radiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about main outcomes of the study

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of radiation oncology of Iran university of medical sciences

What processes are involved for a request to access data/document

Sending the request in writing or by email to the authors

Comments