

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the response and treatment complications of neoadjuvant chemo radiotherapy versus neoadjuvant radiotherapy in larger than 5 centimeter high grade soft tissue sarcoma of extremity between years 2018-2021

Protocol summary

Study aim

Comparing the pathological response to treatment between neoadjuvant chemoradiotherapy and radiotherapy alone. Comparing treatment-induced toxicities between neoadjuvant chemoradiotherapy and radiotherapy alone. Comparing local recurrence, distant metastasis, and post-op mortality, post-op complications rates between two groups. Comparing median overall survival and disease-free survival between two groups.

Design

Two arm parallel-group randomized trial with blinded data analysis and outcome assessment

Settings and conduct

This study is conducted in hospital settings. The participants are selected from the referring patients. After providing informed consent they are randomized into two intervention groups. The data is coded and then analyzed by a blinded analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pathological diagnosis of soft tissue sarcoma in extremity; tumor size over 5 cm based on CT scan or MRI. Exclusion criteria: not tolerating chemotherapy due to underlying renal, hepatic or cardiac problems or insufficient bone marrow reserve; recurrent or metastatic tumors; pregnancy or breastfeeding.

Intervention groups

Arm 1: 3D conformal radiotherapy with 46-50 Gy in 23-25 fractions concomitant with 3 cycles of chemotherapy including Epirubicin and Ifosfamide then surgery. Arm 2: 3D conformal radiotherapy with 46-50 Gy in 23-25 fractions without chemotherapy then surgery.

Main outcome variables

Pathological response to neoadjuvant treatments; treatment-induced toxicities; treatment tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150929024266N4**

Registration date: **2019-11-24, 1398/09/03**

Registration timing: **prospective**

Last update: **2019-11-24, 1398/09/03**

Update count: **0**

Registration date

2019-11-24, 1398/09/03

Registrant information

Name

Reza Ghalehtaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2520

Email address

r-ghaletaki@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the response and treatment complications of neoadjuvant chemo radiotherapy versus neoadjuvant radiotherapy in larger than 5 centimeter high grade soft tissue sarcoma of extremity between years 2018-2021

Public title

Preop chemoradiotherapy for sarcoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pathological diagnosis of soft tissue sarcoma in extremity
Tumor size over 5 cm based on CT scan or MRI

Exclusion criteria:

Not tolerating chemotherapy due to underlying renal, hepatic or cardiac problems or insufficient bone marrow reserve
Recurrent or metastatic tumors
Pregnancy or breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

We opted for permuted block randomization for individuals by random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

We coded the data as each treatment group has a letter determining it so the data analyzer was blinded to the randomization. Others were not blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice-Chancellor in Research Affairs- Tehran University of Medical Sciences

Street address

Vice-chancellor of research and technology, 6th floor, Central building of Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.TUMS.VCR.REC.1397.1039

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

Soft tissue sarcoma of the extremities

ICD-10 code

C49

ICD-10 code description

Malignant neoplasm of other connective and soft tissue

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

Treatment-induced toxicities

Timepoint

Weekly during intervention, 4, 12 and 24 weeks after intervention

Method of measurement

Interviewing patient and physical examination including inspection and palpation, lab data and imaging

2**Description**

Pathological response

Timepoint

After surgery

Method of measurement

Inspection of surgical specimen by the pathologist and defining the extent of tumor tissue necrosis

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

Post-op complications

Timepoint

4 weeks after surgery

Method of measurement

Interviewing and examining the patient

2

Description

Local recurrence

Timepoint

6,12 and 24 month after surgery

Method of measurement

Physical exam and imaging

3

Description

Distant metastasis

Timepoint

6,12 and 24 month after surgery

Method of measurement

Physical exam and imaging

Intervention groups

1

Description

Intervention group: 3DCRT 46-50Gy/23-25 fr plus
Concurrent Chemotherapy with Epirubicin and Ifosfamide
and then Surgical Resection

Category

Treatment - Other

2

Description

Control group: 3DCRT 46-50Gy/23-25 fr without
Chemotherapy and then Surgical Resection

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer institute

Full name of responsible person

Ebrahim Esmati

Street address

Imam Khomeini Hospital Complex, Dr. Qarib Ave.,
Keshavarz Blvd.

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eb_esmati@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Street address

No 206, First Floor, Official Building, Medical Faculty,
Poursina Street, 16th Azar Street, Keshavarz Blvd.

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research@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Ghalehtaki

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Department of Radiation Oncology, Cancer Institute,
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Person responsible for scientific inquiries

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Web page address

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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The study protocol (complete), Informed consent (only the blank template), Clinical study report (as the published article)

When the data will become available and for how long

6 month after the end of the study

To whom data/document is available

Only to academic individuals.

Under which criteria data/document could be used

The written request is mandatory by email emphasizing the mentioning of study conductors in case of using data

From where data/document is obtainable

By contacting this email address: rezaght@gmail.com

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

The study conductors will evaluate each request due to applicants' CV and scientific portfolio. The requests will be responded by 1 month after receiving an email.

Comments