Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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 o 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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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