Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of low dose radiotherapy on pain relief, performance score, and quality of life in patients with knee joints degenerative disorders

Protocol summary

Study aim
This study will assess the effects of radiotherapy on reduction of severity of pain and improvement of performance score and quality of life in patients with osteoarthritis of knee.

Design
Phase 3 Randomised, placebo controlled, parallel group trial with double blinded outcome assessment on 160 patients. Randomisation will be done by table of random numbers.

Settings and conduct
This study will be performed at radiotherapy units of Vasei Hospital of Sabzevar and Shaid Rajaee Hospital of Babolsar. Patients, physicians and outcome assessor will be blinded regarding the groups of patients.

Participants/Inclusion and exclusion criteria
Patients with osteoarthritis of knee with minimum age of 50 years will be enrolled if they have no pervious history of radiotherapy of affected knee.

Intervention groups
In the intervention group, patients will receive radiotherapy every other day at the daily dose of 0.5 gray for 6 sessions.

Main outcome variables
Severity of pain, performance score, and quality of life of patients will be assessed before and after the intervention.

General information

Reason for update
The name of Shahid Rajaei Hospital of Babol University of Medical Sciences as one of the recruitment centers from the beginning in the process of registering the project protocol in the Iranian Registry of Clinical Trials and its approval in the ethical committee of that institution before the study, the code obtained from the ethics committee not mentioned in the Iranian Registry of Clinical Trials, which is corrected now in the research data on the the Iranian Registry of Clinical Trials.

Acronym
RTOA

IRCT registration information
IRCT registration number: **IRCT20160706028815N6**
Registration date: **2020-12-01, 1399/09/11**
Registration timing: **prospective**

Last update: **2022-06-24, 1401/04/03**
Update count: **1**

Registration date
2020-12-01, 1399/09/11

Registrant information

Name
Seyed Alireza Javadinia

Name of organization / entity
Department of Oncology, Omid Hospital, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of low dose radiotherapy on pain relief, performance score, and quality of life in patients with knee joints degenerative disorders

Public title
Effectiveness of radiotherapy on pain, performance score, and quality of life in patients with knee joints osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
knee joints osteoarthritis Age equal and more than 50 years
Exclusion criteria:
Previous history of radiotherapy of affected joint

Age
From **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
The table of random numbers will be used for the randomization. Both groups will be matched in term of gender and age. The the envelope method is that the envelopes will be prepared and printed by one of the members of the research team and random numbers will be prepared by Randomaize.com and will be placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study will be explained to the person who meets the inclusions criteria, and the person will sign the informed consent form and will take an envelope and then will open to enter the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients, physicians (rheumatologist and radiation oncologist), and outcome assessor will be blinded regarding the group of patients. Closed envelope method will be used for blinding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, Vice Chancellor for Research and Technology
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114

Approval date
2020-11-22, 1399/09/02

Ethics committee reference number
IR.MEDSAB.REC.1399.121

2

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Ganj Afrooz Ave
City
Babol
Province
Mazandaran
Postal code
4717647745

Approval date
2021-01-23, 1399/11/04

Ethics committee reference number
IR.MUBABOL.REC.1399.453

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Severity of pain

Timepoint
Before the intervention, at the completion of the

intervention, and one, three, and six months after intervention

Method of measurement

Visual analog scale

2

Description

Performance status

Timepoint

Before the intervention, at the completion of the intervention, and one, three, and six months after intervention

Method of measurement

von Pannewitz score

3

Description

Quality of life

Timepoint

Before the intervention, at the completion of the intervention, and one, three, and six months after intervention

Method of measurement

The 36-Item Short Form Health Survey questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the radiotherapy group, patients will receive radiotherapy with a daily dose of 0.5 gray for 6 days, every other day.

Category

Treatment - Devices

2

Description

Control group: In the placebo group, patients will receive radiotherapy with a daily dose of 0 gray for 6 days, every other day.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Educational and Medical Center

Full name of responsible person

Seyed Alireza Javadinia

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Vasei hospital , Shohadaye Hasteii Blvd

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Web page address

https://medsab.ac.ir/index.aspx?pageid=339&p=1

2

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital

Full name of responsible person

Danial Fazilat-Panah

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Shariati Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

Street address

Tohid Shahr BLV.

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Province

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GhoratF@medsab.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Sabzevar University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
50
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
Sabzevar University of Medical Sciences
Full name of responsible person
Seyed Alireza Javadinia
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Web page address
http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011136

Person responsible for scientific inquiries

Contact
Name of organization / entity
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http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011136

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Alireza Javadinia

Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Web page address
http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011136

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
Deidentified demographic information and data about the primary outcome measures will be shared.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
Data will be only available for people working in academic institutions.
Under which criteria data/document could be used
Data will only be shared for research oriented conditions.
From where data/document is obtainable
In order to access the data, applicant should send an request email to Dr Seyed Alireza Javadinia at javadinia.alireza@gmail.com.
What processes are involved for a request to access data/document
After receiving an official request, communication will be performed by Ethics Committee of Sabzevar University of medical Sciences for further authorizations.
Comments