

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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 Rajaei 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.

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)

Phone

+98 51 3802 2736

Email address

javadiniaa941@mums.ac.ir

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

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

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

Street address

Vasei hospital , Shohadaye Hasteii Blvd

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javadinia.alireza@gmail.com

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

Street address

Shariati Ave.

City

Babol

Province

Mazandaran

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Email

drfazilatpanah@gmail.com

Web page address

<http://rajaee.mubabol.ac.ir/>

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.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

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Email

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
Street address
Ganz Afroz Ave.
City
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Phone
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Fax
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Email
rezaghadimi@yahoo.com

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

Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Radiotherapy ward, Vasei Hospital, Shohaeye Hasteii BLV.
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Fax
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javadinia.alireza@gmail.com
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
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Alireza Javadinia
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Radiotherapy ward, Vasei Hospital, Shohaeye Hasteii BLV.
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Province
Razavi Khorasan
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Email
javadinia.alireza@gmail.com
Web page address
http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011136

Person responsible for general inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Seyed Alireza Javadinia
Position

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

Street address

Radiotherapy ward, Vasei Hospital, Shohaeye Hasteii BLV.

City

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Fax**Email**

javadinia.alireza@gmail.com

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