Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

First Experience of Intra-operative Radiation Therapy (IORT) during Kyphoplasty in Patients with Spinal Metastasis in Iran

Protocol summary

Study aim

Addition of Intra-operative Radiation Therapy (IORT) to conventional kyphoplasty in patients with spinal metastasis to asses the effects of this approach in follow-up period

Design

In this prospective clinical trial, 10 patients with spinal metastasis candidate for Kyphoplasty, will undergo IORT and their clinical, neurological and functional status will be evaluated in pre- and post-operative follow-up periods.

Settings and conduct

This prospective clinical trial will comprise 10 patients diagnosed with spinal metastasis who will be candidates of spinal column Kyphoplasty following application of inclusion and exclusion criteria and will receive radiation during their surgery (IORT) and will be assessed and followed-up in both short and long-term post-operative periods, regarding evaluation of potential complications and neurological status.

Participants/Inclusion and exclusion criteria

It is predicted that 10 patients between 18 to 80 years with confirmed diagnosis of spinal metastasis by radiological and histopathological evaluations will enroll in to this study. Also, cases with previous history of IORT to same involved level, presence of primary bone or neural tissue tumors of spinal column in same desired level, presence of any localized soft tissue infection or systemic infection leading to patient's state deterioration, presence of underlying anatomic disorder of spinal column which can lead to inability of insertion and maintenance of spinal applicators and presence of previous spinal column fractures or osteoporosis will be excluded from the study.

Intervention groups

All of the predicted ten patients with spinal metastasis will be candidates of Kyphoplasty surgical procedure and will receive IORT by individualized applicators with specific dosage based on patient's biomechanic features.

Main outcome variables

Evaluation of pain; performance ability; neurological status

General information

Reason for update

Acronym

IR-K-IORT

IRCT registration information

IRCT registration number: **IRCT20160108025901N1**
Registration date: **2019-12-12, 1398/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-12, 1398/09/21**
Update count: **0**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name
Amir Nikouei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2665 7213
Email address
amirnikouei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-30, 1398/09/09

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
First Experience of Intra-operative Radiation Therapy (IORT) during Kyphoplasty in Patients with Spinal Metastasis in Iran

Public title
Intra-operative Radiation Therapy (IORT) in patients with spinal metastasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of spinal metastasis by radiological evaluation Confirmed diagnosis of spinal metastasis by histopathological evaluation
Exclusion criteria:
Previous history of Intra-operative Radiation therapy (IORT) to the same involved location Presence of primary bone tumors or neural tissue tumors of spine Presence of any local soft tissue infection or systemic infection Presence of underlying anatomic disorder of spinal column
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Yaman Street, Velenjak, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-12-19, 1396/09/28
Ethics committee reference number
IR.SBMU.MSP.REC.1396.685

Health conditions studied

1

Description of health condition studied
Spinal metastasis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Pre-operative period; 2nd week, 1st month, 2nd month and 6 month post-operative period
Method of measurement
Visual Assessment Score (VAS) questionnaire

2

Description
Individual's ability of performance
Timepoint
Pre-operative period; 2nd week, 1st month, 2nd month and 6 month post-operative period
Method of measurement
Karnofsky Performance Scale (KPS) questionnaire

3

Description
Neurological status
Timepoint
Pre- and post-operative period
Method of measurement
Neurological examination

4

Description
Assessment of patient's disability
Timepoint
Pre-operative period; 2nd week, 1st month, 2nd month and 6 month post-operative period
Method of measurement
Oswestry Disability Index (ODI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
All of the predicted ten patients with spinal metastasis will be candidates of Kyphoplasty surgical procedure and will receive IORT by individualized applicators with specific dosage based on patient's biomechanic features.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Afsoun Seddighi
Street address
Shohada Tajrish Hospital, Shahrdari St, Tajrish Sq
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8001
Email
afsoun.seddighi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Saied Seddighi
Street address
Shahid Beheshti University of Medical Sciences, Yaman Street, Velenjak, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
a_sedighi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Nikouei
Position
Doctor of Medicine
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Shohada Tajrish Hospital, Shahrdari St, Tajrish Sq
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8001
Email
amirnikouei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afsoun Seddighi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Shohada Tajrish Hospital, Shahrdari St, Tajrish Sq
City
Tehran
Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8001

Email

afsoun.seddighi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Nikouei

Position

Doctor of Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Shohada Tajrish Hospital, Shahrdari St, Tajrish Sq

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8001

Email

amirnikouei@sbmu.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All of the data will be sharedfollowing unidentification of subjects.

When the data will become available and for how long

Initiation of data access following publication is based upon publishing journal's policies.

To whom data/document is available

All of the researchers of scientific assemblies

Under which criteria data/document could be used

To evaluate the results of this novel therapeutic approach

From where data/document is obtainable

Through e-mail

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

By send an official request to department of research of university following relevant approvals

Comments