

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 assess 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

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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 shared following 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