

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Metastatic bone pain palliation using 177Lu/153Sm-EDTMP cocktail: a clinical trial

Protocol summary

Study aim

Metastatic bone pain palliation using cocktail of 177Lu/153Sm-EDTMP

Design

After obtaining consent from the patients, they will receive 177Lu/153Sm-EDTMP cocktail to relieve their pain. The number of patients will be 25, and they will be followed for 12 weeks after injection. Patients will be evaluated for pain and side effects every week and the pain score form will be filled for them. CBC testing will be performed weekly. At the end of three months, all patients will be evaluated on the effect of the drug and the amount of bone marrow suppression.

Settings and conduct

The project will be conducted at Namazai Hospital in Shiraz. Patients will be referred from the oncology department. A complete biography about matching the location of pain with the patient's bone scan, the amount and type of medication and ..., will be obtained from the patients and, if the requirements for palliative therapy are available, the patients will be registered for palliative care. All patients will be given an informed consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cancer patients with bone metastasis and with a positive bone scan according to pain location, maximally one month before treatment; Suitable CBC for at least one week before treatment; Normal liver and kidney function; Exit conditions: Inappropriate function of liver or kidney; WBC less than 1500; platelets less than 100000; hemoglobin less than 9; Spinal cord pressure; pathologic fractures; mismatch of pain site and bone involvement

Intervention groups

The 177Lu /153Sm-EDTMP cocktail is prepared from the Iran Atomic Energy Organization and 0.5 mCi/kg of each radioactive substance is injected for patients with bone metastases. The drug is administered as a single injection and patients will be followed up for 12 weeks (3 months).

Main outcome variables

The level of pain result from bone metastases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180203038601N1**

Registration date: **2018-04-08, 1397/01/19**

Registration timing: **retrospective**

Last update: **2018-04-08, 1397/01/19**

Update count: **0**

Registration date

2018-04-08, 1397/01/19

Registrant information

Name

Farnaz Khajeh-Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5320

Email address

khajehrahimi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Metastatic bone pain palliation using 177Lu/153Sm-EDTMP cocktail: a clinical trial

Public title

The effect of Lu-177-EDTMP-Sm-153 complex on bone pain palliation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cancerous patients with metastatic lesions in bone and with a positive bone scan coincident with pain location, maximally one month before treatment Suitable CBC at least one week before treatment Normal liver and kidney function

Exclusion criteria:

Inappropriate function of liver or kidney

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **25**

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 Shiraz University of Medical Sciences

Street address

Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2016-09-07, 1395/06/17

Ethics committee reference number

IR.SUMS.MED.REC.1395.18

Health conditions studied**1****Description of health condition studied**

Pain caused by bone metastases

ICD-10 code

M89.8

ICD-10 code description

Other specified disorders of bone

Primary outcomes**1****Description**

Pain caused by bone metastases

Timepoint

Every week for at least 12 weeks

Method of measurement

Completing the pain score form

Secondary outcomes

empty

Intervention groups**1****Description**

The 177Lu /153Sm-EDTMP cocktail is prepared from the Iran Atomic Energy Organization and 0.5 mCi/ kg of each radioactive substance is injected for the patients with bone metastases who fill out informed consent form . The drug is administered as a single injection and patients will be followed up for 12 weeks (3 months). Patients are weekly evaluated for pain and side effects and pain score form will be filled for pain assessment. CBC test will be performed weekly to assess the most common side-effect that is bone marrow suppression. At the end of three months, all patients are evaluated for the effect of the drug and the amount of bone marrow suppression.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi Hospital

Full name of responsible person

Mehr Sadat Alavi

Street address

Namazi Square

City

Shiraz

Province

Fars

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14336 - 71348

Phone

+98 71 3612 5730

Email

khajehrahimi@sums.ac.ir

Position

Scientific Member

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

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City

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Email

alavimh@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mehr Sadat Alavi

Street address

Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

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Phone

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Email

khajehrahimi@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mehr Sadat Alavi

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mehr Sadat Alavi

Position

Scientific Member

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

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alavimh@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farnaz Khejeh-Rahimi

Position

Nuclear medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Nuclear Medicine

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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 data is related to the thesis

When the data will become available and for how long

6 Months

To whom data/document is available

Supervisors and project partners

Under which criteria data/document could be used

after pressing the data

From where data/document is obtainable

Project manager

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

Sending email to the project manager

Comments