

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of Lu-177- HEDMP for bone pain palliation of bone metastasis in breast cancer

Protocol summary

Summary

The present study is evaluation of therapeutic effects of ¹⁷⁷Lu- EDTMP for metastatic bone pain palliation. ¹⁷⁷Lu-EDTMP was prepared by IAEA with standard protocol. Thirty patients with confirmed bone metastasis by recent bone scan were referred to nuclear medicine ward. Renal function test, and baseline CBC were evaluated as exclusion criteria. Validated Persian version of Brief Pain Inventory short form (BPI-sf) was used to evaluate the efficiency of intervention. 0.8 mCi/kg of body weight of Lu- EDTMP in form of sterile IV Injection was administered. Blood and urine sample were collected for dosimetric studies. Bone scan in first, third and seventh day after injection were done. Questionnaire were also been filled by same expert physician every two weeks while CBC and RFT were also been checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109217611N1**
Registration date: **2014-03-20, 1392/12/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-20, 1392/12/29

Registrant information

Name

Mehrossadat Alavi

Name of organization / entity

Shiraz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5319

Email address

alavimh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Lu-177- HEDMP for bone pain palliation of bone metastasis in breast cancer

Public title

Clinical trial of Lu-177- HEDMP for bone pain palliation of bone metastasis in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Severe metastatic bone pain in breast cancer; positive bone scan in recent 1 month corresponding to the painful regions ; normal recent CBC (WBC>2400/ul--Platelet>60000/UL) Exclusion criteria: Negative bone scan ; Pathological fracture of the vertebrae ; WBC<2400/ul---Platelet<60000/ul ; incooperative patients

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 30

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 Commetee of Shiraz university of Medical Sciences

Street address

4th flopor, vice chancellor of research-Shiraz University of Medical Sciences-Zand Street

City

Shiraz

Postal code

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

CT-P-92-2039

Health conditions studied

1

Description of health condition studied

BREAST CANCER

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

SEVERITY OF PAIN

Timepoint

every 2 weeks up to 12 weeks

Method of measurement

questionnaire-By call

Secondary outcomes

1

Description

reduced morbidity- reduce sedative consumption

Timepoint

12 weeks after drug administration

Method of measurement

questionnaire

Intervention groups

1

Description

Single dose slow IV injection of 0.8 mci/kg of Lu177 EDTMP and follow-up by questiunare and CBC measurement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

nuclear medicine departement

Full name of responsible person

Mehrossadat Alavi

Street address

Nuclear Medicine Departement,Namazee Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

SeyyedBasir Hashemi

Street address

4th flopor, vice chancellor of research, Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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

empty

Domestic or foreign origin*empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty*

Shiraz

Postal code**Phone**

+98 71 1612 5319

Fax**Email**

alavimh@sums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**Nuclear medicine departement, Shiraz University of
Medical Sciences**Full name of responsible person**

Mehrossadat Alavi

Position

Associate professor

Other areas of specialty/work**Street address**

Nuclear Medicine Departement-Namazee Hospital

City

Shiraz

Postal code**Phone**

+98 71 1612 5319

Fax**Email**

alavimh@sums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**Nuclear Medicine Departement, Shiraz university of
Medical Sciences**Full name of responsible person**

Mehrossadat Alavi

Position

Associate Professor

Other areas of specialty/work**Street address**

Nuclear Medicine Departement-Namazee Hospital

City**Postal code****Phone**

+98 71 1647 4835

Fax**Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nuclear Medicine Departement

Full name of responsible person

Mehrossadat Alavi

Position

Associate professor

Other areas of specialty/work**Street address**

Nuclear Medicine Departement-Namazee Hospital

City**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*