Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of repeated Prescription of 177Lu-EDTMP combined with docetaxel and prednisone versus docetaxel and prednisone alone in relieving pain in patients with prostate cancer metastatic to bone. A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effectiveness of double administration of 177-Lu-EDTMP radiopharmaceutical with prednisolone with prednisolone versus administration of alone docetaxel with prednisolone in relieving the pain of bone metastases in patients with prostate cancer

Design

In this study, a randomized clinical trial (Phase III) was piloted on 30 patients.Randomization is of the limited randomization type

Settings and conduct

The place of work will be Besat Clinic in Rasht.Eligible patients are randomly divided into two groups with equal ratios.The study will be double blinded . The patient receives the drug (intervention or comparison group) in sealed packets that are coded. The coding is done by one of the project partners and the doctor, the evaluator and the data collector are blind.

Participants/Inclusion and exclusion criteria

Patient over 18 years of age, absolute neutrophil count greater than or equal to 10^9 × 1.5 per liter, platelets greater than or equal to 10^9 × 100 per liter,serum creatinine less than 150 µM Liters , total bilirubin less than or equal to 1.5 times normal, ALT and AST less than or equal to 2.5 times normal. Patients who have previously used Dostoxel or have been exposed to 177Lu-EDTMP radiopharmaceuticals will not be eligible for the study. Patients should be in stage 4 disease

Intervention groups

Intervention group:Patients receive ten cycles of docetaxel (75 mg / m2) in three weeks with double radiopharmaceutical injection of 177Lu-EDTMP (40 mg / kg in the first injection and 20 mg / kg / kg in the second injection). patients will take prednisolone orally at a dose of 5 mg per day. control group: Patients receive ten cycles of docetaxel (75 mg / m2) in three weeks. patients will take prednisolone orally at a dose of 5 mg per day.

Main outcome variables

Patient pain evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042892N2**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date

2021-04-22, 1400/02/02

Registrant information

Name

Mona Haddad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of repeated Prescription of 177Lu-EDTMP combined with docetaxel and prednisone versus docetaxel and prednisone alone in relieving pain in patients with prostate cancer metastatic to bone. A Randomized Clinical Trial

Public title
Evaluation of repeated Prescription of 177Lu-EDTMP combined with docetaxel and prednisone versus docetaxel and prednisone alone in relieving pain in patients with prostate cancer metastatic to bone. A Randomized Clinical Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with prostate cancer with confirmed histological evidence Bone scan results confirmed metastatic bone prevelance Patients enter the study in the metastatic stage The absolute number of neutrophils is greater than or equal to 10^9 × 1.5 per liter Platelet value greater than or equal to 10^9 × 100 per liter Patients with good renal function (serum creatinine less than 150 µM / L) Good liver function (total bilirubin less than or equal to 1.5 times normal ALT and AST less than or equal to 2.5 times normal
Exclusion criteria:
Patients who have already been treated with docetaxel Patients who have already received 177Lu-EDTMP
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is of the limited randomization type until all groups (in our study both groups) have an equal sample size and the random allocation law will be used to balance the number of people assigned to each group in End the study (random block method). For this purpose, Random allocation software and SAS software can be used, which SAS software will be more appropriate. In addition, the websites www.randomization and www.graghpad.com/quickcalcs/index.cf are available and the second website will be used for this purpose.
Blinding (investigator's opinion)
Double blinded
Blinding description
Since one group of patients (intervention group) receives one drug more than the control group, which is actually the same as the radiopharmaceutical 177Lu-EDTMP, and because of the use of radiopharmaceuticals, it is not possible to use placebo, so patients in this study can not be blinded. But the doctor and the main researcher and the evaluator and data collector are blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Parastar Ave
City
Rasht
Province
Guilan
Postal code
41937-13111
Approval date
2021-01-20, 1399/11/01
Ethics committee reference number
IR.GUMS.REC.1399.519

Health conditions studied

1

Description of health condition studied
Prostate cancer
ICD-10 code
C-61
ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Patient pain relief
Timepoint

Assessment periods from the day of injection and 4, 8, 12, 16, 20 and 24 weeks after injection

Method of measurement

Patients complete a visual assessment of pain (VAS) and a questionnaire of quality of life before each course of treatment until the disease progresses. The amount of pain is determined using standard scoring criteria

Secondary outcomes

1

Description

Side effects such as bone marrow suppression or a decrease in the number of lymphocytes and platelets

Timepoint

During the study

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group: Patient receive ten courses of dostoxel (75 mg / m2) in three weeks with two injections of 177Lu-EDTMP radiopharmaceutical (40 mg / kg in the first injection and 20 mg / kg / kg in the second injection). In the first injection, they receive 2590 megabecrels and in the second injection, 1295 megabecrels of radiopharmaceuticals. The radiopharmaceutical injection will be done after the third and sixth period of docetaxel administration. All patients will take prednisolone orally at a dose of 5 mg daily.

Category

Rehabilitation

2

Description

Control group: Patient receive ten courses of dostoxel (75 mg / m2) in three weeks.All patients will take prednisolone orally at a dose of 5 mg daily.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat clinic

Full name of responsible person

Dr. Seyed Hossein Mirpour

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Enghelab Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Dr. Cyrus Amir alavi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable