

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Therapeutic and Adverse Effects of Leupromer (Iranian Formulated LHRH agonist) and Eligard in patients with Metastatic Prostate Cancer

Protocol summary

Summary

This phase II clinical trial will be carried out on patients with metastatic prostate cancer who refer to Shohadaaye-Tajrish Urology clinic. Metastatic prostate cancer patients without previous treatment will be allocated to two groups and receive one of treatments (Leupromer or Eligard) as study protocol. Sample size in study and control arm is 33 and 65 retrospectively. The outcome will be assessed using serum testosterone level and PSA and LH test after 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206131030N10**
Registration date: **2012-12-27, 1391/10/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-27, 1391/10/07

Registrant information

Name

Mahdi Jalili

Name of organization / entity

Hematology-Oncology & SCT Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2662

Email address

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Recruitment status

Recruitment complete

Funding source

Iran Polymer and petrochemical institute

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Therapeutic and Adverse Effects of Leupromer (Iranian Formulated LHRH agonist) and Eligard in patients with Metastatic Prostate Cancer

Public title

Comparison of Therapeutic and Adverse Effects of Leupromer (Iranian Formulated LHRH agonist) and Eligard in patients with Metastatic Prostate Cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Patient with metastatic prostate cancer who examined by paraclinical diagnostics. (i.e.: needle biopsy of prostate, pathologic trans rectal sonography bone scan, CT-scan and MRI) and assessed their bone and viscera; 2- Must be Iranian; 3-Signed the testimonial form by own awareness. 4-Confidency of patient cooperation with administering drug; 5-Assistance of patient to come with scheduled program. Exclusion criteria: 1-Disorder in hypothalamus-hypophysis-gonadal axis; 2-Previous treatment with GnRH analog or other hormonal treatment or chemotherapy in last three month; 3-Radioteraphy in last two month; 4-Malignant with active origin; 5-Need to adjuvant treatment; 6-

Urinary obstruction or spinal cord compression; 7- Administering with other drug (cooperating with another study); 8- Dissatisfaction of patient; 9-Probability of impossibility of following by patient; 10-drug addiction; 11- allergy to GnRH analogs or any kind of GnRH.

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 98

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 6th floor of Tehran University of Medical Sciences, Ghods St., Keshavarz blv, Tehran, Iran

City

Tehran

Postal code**Approval date**

2012-10-28, 1391/08/07

Ethics committee reference number

124-91/8/7

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

Metastatic prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

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

Ratio of serum PSA level regarding to baseline

Timepoint

28, 56 and 84 day after beginning of treatment

Method of measurement

PSA tumor marker (ng/ml)

Secondary outcomes**1****Description**

Testosterone serum level

Timepoint

28, 56 and 84 day after beginning of treatment

Method of measurement

Testosterone blood level (ng/dl)

2**Description**

LH serum level

Timepoint

28, 56 and 84 day after beginning of treatment

Method of measurement

LH blood level (IU/L)

3**Description**

Side effect frequency

Timepoint

Three month after beginning day of treatment

Method of measurement

Examination and following treatment

4**Description**

Bone pain decreasing frequency

Timepoint

Three month after beginning day of treatment

Method of measurement

Examination and following treatment based on 1-10 score

5**Description**

Frequency of reduction in urinary pain

Timepoint

Three month after beginning day of treatment

Method of measurement

Examination and following treatment based on 1-10 score

6**Description**

Frequency of reduction in urinary symptom
Timepoint
Three month after beginning day of treatment
Method of measurement
Examination and following treatment based on 1-10 score

Intervention groups

1

Description
Leupromer 7.5mg every 28 day for 3 times
Category
Treatment - Drugs

2

Description
Eligard 7.5mg every 28 day for 3 times
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Urology Clinic
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Polymer and petrochemical institute
Full name of responsible person
Dr. Alireza Nateghi
Street address
Iran Polymer and Petrochemical Institute (IPPI) P.O.
Box 14965/115
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Polymer and petrochemical institute
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

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Hasanzade
Position
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact
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Varian Daroo Pazhoh
Full name of responsible person
Dr Hamid Mobedi
Position
PhD

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

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Fax**Email****Web page address****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