Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 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

m_jalili@farabi.tums.ac.ir

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-Paetient 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 assessd 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-Assitance 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-Radioteraohy 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,6 th 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

Urology assistance

Other areas of specialty/work

Street address

Shohadaye Tajrish Urology Clinic, Shahdari Ave, Tajrish circle

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soheilahasoory@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Jalili Hossieni

Position

Associate Professor/Urologist

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Varian Daroo Pazhoh

Full name of responsible person

Dr Hamid Mobedi

Position

PhD

Other areas of specialty/work
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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