

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of Therapeutic Effects of variopeptyl (Iranian Formulated LHRH agonist) in patients with Metastatic Prostate Cancer

#### Protocol summary

##### Summary

Purpose: To assess the efficacy of variopeptyl in decreasing serum testosterone and PSA level in patients with metastatic prostate cancer (It is our objective to evaluate the effect of this drug in reducing the level of Prostate specific antigen and serum Testosterone).  
Inclusion Criteria: All patients with metastatic prostate cancer without age limitation who are referred to urology clinic of Imam Khomeini Hospital, Filling consent form and Not receiving hormone therapy before  
Exclusion Criteria: 1. dysfunction in Hypothalamic - pituitary - gonadal axis 2. Simultaneous presence of active malignancy with different origin 3. Require the other treatments (chemotherapy, radiotherapy) 4. Inability to obtain consent due to dissatisfaction or intellectual problems 5. History of hypersensitivity to GnRH, GnRH analogs 6. History of bilateral orchiectomy  
Method: 47 consecutive patients with metastatic prostate cancer who are candidates for receiving LHRH agonist are potential eligible participants. Written Informed consent will be obtained from all patients. In this study, 3.75 mg of variopeptyl will be injected subcutaneously every 28 days and PSA and serum Testosterone is measured before intervention and at 1, 3 and 6 month intervals.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201410289819N5**  
Registration date: **2015-07-09, 1394/04/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-07-09, 1394/04/18

#### Registrant information

##### Name

Mohammadreza Nowroozi

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2764

##### Email address

uorc@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research Tehran University of Medical Sciences varian daru Pharmaceutical Company

#### Expected recruitment start date

2014-11-08, 1393/08/17

#### Expected recruitment end date

2015-11-21, 1394/08/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of Therapeutic Effects of variopeptyl (Iranian Formulated LHRH agonist) in patients with Metastatic Prostate Cancer

#### Public title

Efficacy of variopeptyle in treating MPCa

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: All patients with metastatic prostate cancer without age limitation who are referred to urology clinic of Imam Khomeyni Hospital, Filling consent form

and Not receiving hormone therapy before Exclusion Criteria:1. dysfunction in Hypothalamic - pituitary - gonadal axis 2. Simultaneous presence of active malignancy with different origin 3. Require the other treatments (chemotherapy, radiotherapy) 4.Inability to obtain consent due to dissatisfaction or intellectual problems 5. History of hypersensitivity to GnRH, GnRH analogs 6. History of bilateral orchiectomy

**Age**

No age limit

**Gender**

Male

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 47

**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 Tehran University Of Medical Sciences

**Street address**

Central Organization Of Tehran University Of Medical Sciences, Qods St, Keshavarz Blvd Tehran

**City**

Tehran

**Postal code****Approval date**

2014-07-20, 1393/04/29

**Ethics committee reference number**

92-03-11-23568-118042

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

prostate cancer

**ICD-10 code**

c61

**ICD-10 code description**

Malignant neoplasm of prostate

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

Testosterone

**Timepoint**

Before intervention, one month after intervention, three months after intervention and six months after intervention

**Method of measurement**

ELISA

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

PSA

**Timepoint**

Before intervention, one month after intervention, three months after intervention and six months after intervention

**Method of measurement**

ELISA

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

Variopeptyl 3.75 milligram ( which is LHRH agonist) each 28 days,until 6 months, subcutaneous,Produced by varian daru company

**Category**

Treatment - Drugs

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

Urology Clinic Of Imam khomeyni Hospital

**Full name of responsible person**

erfan amini

**Street address**

Imam Khomeyni Hospital, Keshavarz Blvd

**City**

Tehran

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

Vice chancellor for research Tehran University of

Medical Sciences

**Full name of responsible person**

Yonesian Masud

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Central Organization of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd

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Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research Tehran 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*

## Person responsible for general inquiries

**Contact**

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Uro oncology research center, Tehran University of Medical Sciences, Tehran, Iran

**Full name of responsible person**

Amini Erfan

**Position**

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## Person responsible for scientific inquiries

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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*