

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Assessment of treatment efficacy and adverse effects of Microrelin in patient with prostate cancer.

#### Protocol summary

##### Summary

Background: It seems that assessment of the efficacy and adverse effects of microrelin as a new agent for treatment of high grade prostate cancer is mandatory. Goal: Assessment of treatment efficacy and adverse effects of microrelin in patient with prostate cancer Method: 40 patients with high grade prostate cancer (GS $\geq$ 8 and PSA $>$ 20) and extraprostatic extension who are not suitable for surgery or patients with bone metastases or pelvic lymph node involvement in lymph node biopsy are selected from urology clinic of shahid labbafinejad medical center. We explain the goals and study designation to all patients at the beginning of study and each patient who accept this performance, finally included in this study. This study has been designed using single blind randomized clinical trial. Adverse side effects will be evaluated subjectively monthly by phone interview and objectively using blood analysis every three months. All patients are assessed using prostate examination by digital rectal examination and biochemical evaluation using blood analysis (CBC, Bun, Cr, Ca, P, SGPT, SGOT, Alkp, PSA, FSH, LH, PRL, Estradiol, and testosterone) every three months. All patients with bone metastases will be re-evaluated annually with whole body bone scan.

#### General information

##### Acronym

Treatment efficacy and adverse effects of Microrelin

##### IRCT registration information

IRCT registration number: **IRCT201109067457N4**

Registration date: **2011-10-09, 1390/07/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-10-09, 1390/07/17

##### Registrant information

###### Name

Shabnam Golshan

###### Name of organization / entity

Urology and Nephrology Research Center (UNRC)

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2256 7222

###### Email address

shgolshan@unrc.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Pooyesh darou company

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2013-04-21, 1392/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of treatment efficacy and adverse effects of Microrelin in patient with prostate cancer.

##### Public title

Assessment of treatment efficacy and adverse effects of Microrelin in patient with prostate cancer.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- High risk prostate cancer with PSA $>$ 20 and/or GS $\geq$ 8 with extraprostatic extension and

unsuitable for surgery. 2- Patients with bone metastases. 3- No history of surgery or radiotherapy for prostate cancer. 4- No history of other malignancy or consumption of other hormonal agents except microrelin. 5- Pelvic lymph node involvement . Exclusion criteria: 1- Surgery or raditherapy for prostate cancer. 2- Microrelin withdrawal 3- Coexistence of other malignancy.

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Urology & Nephrology Research Center, Shahid Beheshti University of Medical Sciences (UNRC)

**Street address**

No#103, 9th Boostan, Pasdaran Ave,

**City**

Tehran

**Postal code**

1666677951

**Approval date**

2010-12-07, 1389/09/16

**Ethics committee reference number**

415/179

**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**

Microrelin or Dipherelin consumption

**Timepoint**

Every 3 month

**Method of measurement**

Blood analysis

**2****Description**

Hemoglubin

**Timepoint**

Every 3 month

**Method of measurement**

Blood analysis

**3****Description**

Prostate Specific Antigen (PSA)

**Timepoint**

Every 3 month

**Method of measurement**

Blood analysis

**4****Description**

Gleason score (GS)

**Timepoint**

At the end of study

**Method of measurement**

Prostate biopsy

**5****Description**

SGOT

**Timepoint**

Every 3 month

**Method of measurement**

Blood analysis

**6****Description**

SGPT

**Timepoint**

Every 3 month

**Method of measurement**

Blood analysis

**7****Description**

Testosteron

**Timepoint**

Every 3 month  
**Method of measurement**  
Blood analysis

## 8

**Description**  
Prolactin  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## 9

**Description**  
LH  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## 10

**Description**  
FSH  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## 11

**Description**  
New changes in bone scan  
**Timepoint**  
Annual  
**Method of measurement**  
Whole body bone scan

## 12

**Description**  
Alkp  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## 13

**Description**  
Calcium  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## 14

**Description**  
Phosphor  
**Timepoint**  
Every 3 month

**Method of measurement**  
Blood analysis

## Secondary outcomes

### 1

**Description**  
Flushing  
**Timepoint**  
Monthly  
**Method of measurement**  
Physical examination

### 2

**Description**  
Bone pain  
**Timepoint**  
Monthly - Annualy  
**Method of measurement**  
Physical examination - Whole body bone scan

### 3

**Description**  
Cardiovascular side effects  
**Timepoint**  
Every 3 month  
**Method of measurement**  
ECG analysis

### 4

**Description**  
Anemia  
**Timepoint**  
Every 3 month  
**Method of measurement**  
Blood analysis

## Intervention groups

### 1

**Description**  
Intervention group: 20 patients with Microrelin (LHRH agonist) injection , 3.75 mg, Deep intramuscular injection, Every 28 days. Duration of assessment:18 months  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: 20 patients with Dipherelin - 3.75 mg - deep intramuscular injection - Every 28 days -Duration of assessment : 18 months  
**Category**  
Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Labbafinejad Medical Center

**Full name of responsible person**

Ali Tabibi, MD, Associate professor of urology

**Street address**

9th Boostan, Pasdaran Ave, Shahid labbafinejad medical center

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Pooyesh darou company

**Full name of responsible person**

Dr. Nayebpour

**Street address**

No#13, 5th st, infront of ministry of government, Fatemi Ave.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Pooyesh darou company

**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**

Urology and Nephrology Research Center (UNRC)

**Full name of responsible person**

Mohammad Hossein Soltani

**Position**

MD, Urologist

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

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mohsenof20@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Urology department of shahid labbafinejad medical center

**Full name of responsible person**

Ali Tabibi

**Position**

Associate professor of urology

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

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dralitabibi@gmail.com

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## Person responsible for updating data

**Contact****Name of organization / entity**

Urology and Nephrology Research Center (UNRC)

**Full name of responsible person**

Ali Mohammad Mirjalili

**Position**

MD, Resident of urology

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aliaskari56@yahoo.com

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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*