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>=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>=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- Coexistance 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
No#103, 9th Boostan, Pasdaran Ave.
City
Tehran
Postal code
Phone
+98 21 2256 7222
Fax
Email
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
No#103, 9th Boostan, Pasdaran Ave.
City
Tehran
Postal code
Phone
+98 21 2258 8016
Fax
Email
dralitabibi@gmail.com
Web page address

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
Other areas of specialty/work
Street address
No#103, 9th Boostan, Padaran Ave.
City
Tehran
Postal code
Phone
+98 21 2258 8016
Fax
Email
aliaskari56@yahoo.com
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