Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparative bioequivalency study (pharmacokinetics-pharmacodynamics) of Variopeptyl® 11.25 mg and Diphereline® 11.25 mg in Patients with non-metastatic or metastatic prostate cancer Volunteers

Protocol summary

Study aim
Evaluation of pharmacokinetic parameters based on measurement of serum triptorelin concentration, Evaluation of pharmacodynamic parameters based on measurement of decreased sex hormone levels (reduction of serum testosterone level to castration level) of patients with non-metastatic or metastatic prostate cancer.

Design
This clinical trial is a bioequivalence study, randomized, double-armed, double-blind, parallel, with a 1: 1 ratio of volunteers.

Settings and conduct
This clinical trial at Isfahan Poursina Research center and Tehran Khatam-al Anbiya hospital begins to accept volunteer patients. This study is double-blind and the patient and the principal investigator are unaware of the type of prescription intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Men between the ages of 50 and 90 • patient with non-metastatic or metastatic prostate cancer whose disease has been diagnosed based on examination and paraclinical procedures. • No cardiovascular, cerebral, renal or hepatic problems. • No history of hormone use, immunosuppressive drugs in the last 2 months • No immune system diseases such as AIDS and .MS • Able and willing to sign informed consent form; Exclusion criteria: • Sensitivity to drugs, especially GnRH-A Previous history of chemotherapy • Other diseases

Intervention groups
All volunteers are randomly divided into two groups after definitive confirmation of non-metastatic or metastatic prostate cancer and one group will receive 11.25 mg of extended-release injectable variopeptyl and the other group will receive 11.25 mg of injectable extended-release drug diphererline.

Main outcome variables
measurement of serum triptorelin concentration

General information

Reason for update
Changes in the study population (According to the principal investigator, the number of people with non-metastatic prostate cancer is very limited, so it is necessary to increase the age range of patients participating in the study from 50 to 70 years to 50 to 90 years. Also adding the population of patients with metastatic prostate cancer to the inclusion criteria).

Acronym

IRCT registration information
IRCT registration number: **IRCT20170225032759N3**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **prospective**

Last update: **2023-04-11, 1402/01/22**
Update count: **3**

Registration date
2021-04-06, 1400/01/17

Registrant information

Name
Amir Mansour Jalali Nadooshan

Name of organization / entity
Varian Pharmed

Country
Iran (Islamic Republic of)

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+98 21 2485 2480

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-02-26, 1400/12/07

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalency study (pharmacokinetics-pharmacodynamics) of Variopeptyl® 11.25 mg and Diphereline® 11.25 mg in Patients with non-metastatic or metastatic prostate cancer Volunteers

Public title
Comparative bioequivalency study (pharmacokinetics-pharmacodynamics) of Variopeptyl® 11.25 mg and Diphereline® 11.25 mg in Patients with non-metastatic or metastatic prostate cancer Volunteers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
• Men between the ages of 50 and 90 • patient with non-metastatic or metastatic prostate cancer whose disease has been diagnosed based on examination and paraclinical procedures. • Without cardiovascular, cerebral, renal and liver problems. • No history of hormone use, immunosuppressive drugs in the last 2 months • No immune system diseases such as AIDS and MS • Able and willing to sign informed consent form

Exclusion criteria:
• Sensitivity to drugs, especially GnRH-A • Previous history of chemotherapy • Other diseases

Age
From **50 years** old to **90 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is based on randomized classification blocks. The randomization sequence will be created using the RandBETWEEN in Excel program.

Blinding (investigator's opinion)
Double blinded

Blinding description
People who in this study will be unaware of the type of intervention prescribed to patients participating in the study are: •Patient • Principal Investigator (Physician) The person who is aware of the type of intervention prescribed to patients in this study is the central staff that patients will refer to during the previous coordination, and based on the random allocation list, one of the two interventions will be prescribed for them.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jerib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2021-03-09, 1399/12/19

Ethics committee reference number
IR.MUI.MED.REC.1399.1142

Health conditions studied

1

Description of health condition studied
non-metastatic or metastatic prostate cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Measurement of triptorelin concentration

Timepoint
at the beginning of study, During 24 hours of hospitalization, 1, 2, 4, 6, 8, 12 hours after drug administration and 2, 3, 7, 14, 21, 28, 31, 35, 42, 60, 65, 75, 80, 84, 90 days will be measured after drug administration.

Method of measurement
[D-Trp6]-LHRH

Secondary outcomes

1

Description
Measurement of PSA level
Timepoint
At the beginning of study, During 24 hours of hospitalization, 1, 2, 4, 6, 8, 12 hours after drug administration and 2, 3, 7, 14, 21, 28, 31, 35, 42, 60, 65, 75, 80, 84, 90 days will be measured after drug administration.
Method of measurement
PSA tumor marker (ng/ml)

2

Description
Measurement of serum testosterone
Timepoint
At the beginning of study, During 24 hours of hospitalization, 1, 2, 4, 6, 8, 12 hours after drug administration and 2, 3, 7, 14, 21, 28, 31, 35, 42, 60, 65, 75, 80, 84, 90 days will be measured after drug administration.
Method of measurement
RIA

3

Description
Measurement of serum FSH
Timepoint
At the beginning of study, During 24 hours of hospitalization, 1, 2, 4, 6, 8, 12 hours after drug administration and 2, 3, 7, 14, 21, 28, 31, 35, 42, 60, 65, 75, 80, 84, 90 days will be measured after drug administration.
Method of measurement
RIA

Intervention groups

1

Description
Intervention group: Ḍiphereline 11.25 mg single dose for 3 months
Category
Treatment - Drugs

2

Description
Intervention group: Variopeptyl 11.25 mg single dose for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Poursina Research Center
Full name of responsible person
Pouria Adeli
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Sepehr Blvd, Salamat Town, Aghababaei Highway, Isfahan.
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2

Recruitment center
Name of recruitment center
Tehran Khatam-al Anbiya hospital
Full name of responsible person
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Tehran، Rashid Yasemi Street، Upper than Mirdamad St.، Vali- Asr St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Varian Pharmed Co
Full name of responsible person
Dr Sepideh Hashemzadeh
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1473896381
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Varian Pharmed Co
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Varian Pharmed Co
Full name of responsible person
Dr Amir mansour Jalali Nadooshan
Position
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Person responsible for updating data

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a.jalali@varianpharmed.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available