

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of two sustained release Triptorelin vials manufactured by Ronak Darou and IPSEN in patients with prostate cancer based on biologic response (serum PSA and Testosterone levels)

Protocol summary

Study aim

The main objective of this study is evaluating bio-equivalency of two sustained release Triptorelin vials manufactured by Ronak Darou and IPSEN in patients with prostate cancer. As determining the blood level of this product is too complicated and could not be done by routine methods, measurement of biologic response to the medication, including serum Prostate Specific Antigen (PSA) and Testosterone levels, is recommended as surrogate of blood level to compare bio-equivalency of generic and brand forms of Triptorelin

Design

Two arm parallel group randomised trial

Settings and conduct

This study will be done in urology clinic of Shahid Labbafinejhad hospital and patients and physicians will be blinded to study arms

Participants/Inclusion and exclusion criteria

50 patients diagnosed with metastatic prostate cancer will be recruited after signing the written consent form

Intervention groups

Patients randomly (using random number table) will be assigned to brand (Diphereline, IPSEN, France) and generic forms of sustained release Triptorelin acetate (Decareline, Ronak Darou, Iran), on a 1:1 basis, 3.75mg by IM injection every 28 days for 3 months.

Main outcome variables

Prostate Specific Antigen (PSA) serum level Testosterone serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090410178N10**
Registration date: **2016-10-29, 1395/08/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-28, 1397/05/06**

Update count: **1**

Registration date

2016-10-29, 1395/08/08

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Ronak Pharm

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of two sustained release Triptorelin vials manufactured by Ronak Darou and IPSEN in patients with prostate cancer based on biologic response (serum PSA and Testosterone levels)

Public title

Bioequivalence study of two Triptorelin vials manufactured by Ronak Darou and IPSEN in patients with prostate cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Metastatic prostate cancer Signing written consent form

Exclusion criteria:

Hypothalamic pituitary gonadal axis dysfunction
Malignancy other than prostate cancer Treatment with other Gonadotropin Releasing Hormone (GnRH) analogues, hormones, radiotherapy or chemotherapy during recent three months Allergy to GnRH, GnRH analogues or to any component of medications

Age

From **18 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **4**
5 ml of venous blood

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using individualized simple randomization method by Rnd function of Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who are candidate to receive triptorelin, based on physician's decision, will be referred to researcher and using pre-designed randomization table will be allocated in study arms. Data will be send to data analyzer using codes and decoding will be done after completion of data analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-07-20, 1395/04/30

Ethics committee reference number

IR.SBMU.PHNM.1395.408

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**

Prostate Specific Antigen (PSA) serum level

Timepoint

Before injection of each dose of medication for 3 months

Method of measurement

Biomerieux Vidas kits

2**Description**

Testosterone serum level

Timepoint

Before injection of each dose of medication for 3 months

Method of measurement

Biomerieux Vidas kits

Secondary outcomes

empty

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

Diphereline (Triptorelin acetate manufactured by IPSEN, France) 3.75mg IM every 28 days for 3 doses

Category

Treatment - Drugs

2

Description

Decareline (Triptorelin acetate manufactured by Ronak Darou, Iran) 3.75mg IM every 28 days for 3 doses

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology clinic, Shahid Labbafinejad hospital

Full name of responsible person

Shadi Ziaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Ronak Pharm

Full name of responsible person

Zahra kourorian

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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

Ronak Pharm

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Associate Professor / Clinical Pharmacy Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data related to primary objectives

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

People working in academic institutions; pharmaceutical companies

Under which criteria data/document could be used

With official letter

From where data/document is obtainable

Mohammad Sistanizad

What processes are involved for a request to access data/document

Data are available 6 months after publication of results

Comments