

# 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

##### Street address

9th Boostan St., Pasdaran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23601

##### Email

shadi\_z73@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Tahereh Shams

##### Street address

Velenjak Street, Shahid Chamran High Way

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 8820 0102

##### Email

T\_shams@yahoo.com

##### 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

##### Street address

3rd Floor, No.85, Gomnam St., Fatemi Sq., Tehran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1431614481

##### Phone

+98 21 8839 0564

##### Email

zkourorian@gmail.com

##### 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

##### Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1991953381  
**Phone**  
+98 218800087  
**Fax**  
**Email**  
sistanizadm@sbmu.ac.ir  
**Web page address**

## Person responsible for scientific 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  
**Street address**  
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway  
**City**  
Tehran  
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## Person responsible for updating data

### 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**  
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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