

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of efficacy of Diphereline and Variopeptyl in treatment of girls with idiopathic central precocious puberty

#### Protocol summary

##### Study aim

comparison of the efficacy and safety of Diphereline 3.75 mg manufactured by IPSEN (France) and Variopeptyl 3.75 mg manufactured by Varian pharmed Co (Iran) in treatment of girls with Central Precocious Puberty (CPP)

##### Design

In this research, 36 eligible girls with Central Precocious Puberty referring to endocrinology clinic of Shahid Sadoughi medical science university of Yazd were chosen purposefully and divided into two control and intervention groups.

##### Settings and conduct

patients after clinical and laboratory examination and confirmation of CPP in endocrinology clinic of Shahid Sadoughi medical science university of Yazd divided and treated into two control and intervention groups, this study is not blinded

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: girls under 8 years, with confirmed central precocious puberty (CPP) after the clinical & laboratory (FSH, LH, Estradiol ) & Uterus and ovaries sonography examinations also Previously, they have not been treated for CPP and signed Informed Consent Form. Exclusion criteria: If the patient's have any ADR to the drug or the patient's dissatisfaction with the continuation of the study.

##### Intervention groups

Diphereline 3.75 mg manufactured by IPSEN (France) and Variopeptyl 3.75 mg manufactured by Varian pharmed Co (Iran)

##### Main outcome variables

Decrease levels of FSH, LH, and Estradiol hormones

#### General information

##### Reason for update

##### Acronym

Central Precocious Puberty (CPP)

##### IRCT registration information

IRCT registration number: **IRCT20170225032759N1**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

##### Registration date

2017-12-03, 1396/09/12

##### Registrant information

###### Name

Amir Mansour Jalali Nadooshan

###### Name of organization / entity

Varian Pharmed

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2485 2480

###### Email address

a.jalali@varianpharmed.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-06-19, 1395/03/30

##### Actual recruitment start date

2016-01-21, 1394/11/01

##### Actual recruitment end date

2016-06-09, 1395/03/20

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of Diphereline and Variopeptyl in treatment of girls with idiopathic central precocious puberty

## Public title

Comparison of efficacy of Diphereline ( IPSEN, France) and Variopeptyl (Varian pharmed, IRAN) in treatment of girls with idiopathic central precocious puberty (CPP)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

girls under 8 years, with confirmed central precocious puberty (CPP) signed Informed Consent Form

### Exclusion criteria:

girls older 8 years

## Age

From **2 years** old to **8 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **36**

Actual sample size reached: **35**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Sadoughi Yazd University of Medical Science

##### Street address

Shahid Sadoughi University of Medical Science, Allam Sq, Safaeiyeh St,

##### City

Yazd

##### Province

Yazd

##### Postal code

8915173160

#### Approval date

2016-01-06, 1394/10/16

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.386

## Health conditions studied

### 1

#### Description of health condition studied

central precocious puberty

#### ICD-10 code

E22.8

#### ICD-10 code description

E22.8

## Primary outcomes

### 1

#### Description

LH

#### Timepoint

before intervention then 28 days after injections (days 0-28-56-84)

#### Method of measurement

Cm

### 2

#### Description

FSH

#### Timepoint

before intervention then 28 days after injections (days 0-28-56-84)

#### Method of measurement

Iu/L

### 3

#### Description

Estradiol

#### Timepoint

before intervention then 28 days after injections (days 0-28-56-84)

#### Method of measurement

Iu/L

## Secondary outcomes

### 1

#### Description

Hight

#### Timepoint

before intervention then 28 days after injections (days 0-28-56-84)

#### Method of measurement

cm

### 2

#### Description

wieght

#### Timepoint

before intervention then 28 days after injections (days 0-28-56-84)

**Method of measurement**

Kg

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

Treatment with use of Diphereline 3.75 mg (triptorelin) manufactured by IPSEN (France) every 28 days for 3 months

**Category**

Treatment - Drugs

**2****Description**

Treatment with use of Variopeptyl 3.75 mg (triptorelin) manufactured by IPSEN (IRAN) every 28 days for 3 months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Endocrinology Clinic of Shahid Sadoughi University of Medical Science

**Full name of responsible person**

Dr. Mahtab ordooei

**Street address**

Safaeiyeh, Allam Sq

**City**

Yazd

**Province**

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**Postal code**

8915173160

**Phone**

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**Email**

dr.ordooei@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Private

**Full name of responsible person**

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**Province**

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**Email**

dr.mansourjalali@gmail.com

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

Yes

**Title of funding source**

Private

**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**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mahtab ordooei

**Position**

Pediatric endocrinology/Phd

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pediatric endocrinology

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mahtab ordooei

**Position**

Pediatric endocrinology/Phd

**Latest degree**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Varian Pharmed

**Full name of responsible person**

Dr. Amir mansour jalali nadooshan

**Position**

PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address****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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available