

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

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dr.ordooei@yahoo.com

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

Private

Full name of responsible person

Mahtab Ordooei

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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

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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