

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of Changes in Electrocardiogram's Intervals During Treatment with Gonadotropin-Releasing Hormone Agonists in Patients with precocious puberty

Protocol summary

Study aim

Evaluation of Changes in Electrocardiogram's Intervals During Treatment with Gonadotropin-Releasing Hormone Agonists in Patients with precocious puberty

Design

A before-after clinical trial on 50 children with precocious puberty without any control group.

Settings and conduct

The electrocardiograms of studied patients were evaluated and compared them before starting treatment with gonadotropin releasing hormones agonists and at 3, 6, 12, and 18 weeks after the treatment in Tabriz Children's Hospital.

Participants/Inclusion and exclusion criteria

Children with precocious puberty referring to the Endocrinology Clinic of Tabriz Children Hospital who had the indication to treat with gonadotropin releasing hormone agonists are included in this study. Patients will not be included in the study if there is any previous cardiovascular disease.

Intervention groups

Children with precocious puberty that Triptorelin will be administered as gonadotrophin hormone agonist.

Main outcome variables

Electrocardiogram

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190314043051N1**

Registration date: **2019-03-18, 1397/12/27**

Registration timing: **prospective**

Last update: **2019-03-18, 1397/12/27**

Update count: **0**

Registration date

2019-03-18, 1397/12/27

Registrant information

Name

Ali Bagherzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3380 1458

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bagherzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Changes in Electrocardiogram's Intervals During Treatment with Gonadotropin-Releasing Hormone Agonists in Patients with precocious puberty

Public title

The Effect of Triptorelin on Electrocardiogram

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children with precocious puberty Referring to
Endocrinology Clinic of Tabriz Children Hospital

Exclusion criteria:

Having any type of previous cardiac disease

Age

From **2 years** old to **9 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical
Sciences

Street address

3rd Floor, No. 2 Central Building, Tabriz University of
Medical Sciences, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665935

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TBZMED.REC.1397.1072

Health conditions studied

1

Description of health condition studied

precocious puberty

ICD-10 code

E30.1

ICD-10 code description

Precocious puberty

Primary outcomes

1

Description

QRS interval duration in electrocardiogram

Timepoint

Before the intervention and 6, 12, and 18 weeks after the
starting of gonadotropin releasing hormone agonists

Method of measurement

Electrocardiography

2

Description

PR interval duration in electrocardiogram

Timepoint

Before the intervention and 6, 12, and 18 weeks after the
starting of gonadotropin releasing hormone agonists

Method of measurement

Electrocardiography

3

Description

QT interval duration in electrocardiogram

Timepoint

Before the intervention and 6, 12, and 18 weeks after the
starting of gonadotropin releasing hormone agonists

Method of measurement

Electrocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Triptorelin (FERRING, Germany) as a gonadotropin-
releasing hormone agonist in the form of 0.1 mg ampule
will be administered as the intramuscular injection once
a month to children with precocious puberty at a dose of
75 µg/kg body weight for at least 18 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Siamak Shiva

Street address

Sheshgelan street

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5136735886

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kodakanhospital@tbzmed.ac.ir

Web page address
<https://childrenhospital.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

Street address
3rd Floor, No. 2 Central Building, Tabriz University of Medical Sciences, University Street

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Siamak Shiva

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

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Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact

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resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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