Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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

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Sheshgelan street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Abolghasem Jouyban
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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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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