Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study the effect of Fluoxetine on Breath Holding Spells in Children who refer to Ghaem hospital of Mashhad

Protocol summary

Study aim
Study the effect of fluoxetine on the treatment of Breath Holding Spells
Design
Clinical trials with community-based and pragmatic control group, parallel groups, randomized with Sealed envelope, which was not blinded and single-centered, included 30 BHS patients
Settings and conduct
The study was single central and was performed in Ghaem hospital of Mashhad and Blindness was not done.
Participants/Inclusion and exclusion criteria
Attacks of breath Holding Spells include cyanotype or pallid at least every 2 weeks, or more
Intervention groups
In the Intervention group BHS Children are given 1 or 2 CC fluoxetine syrup with iron drop for 3 month each morning after breakfast . The fluoxetine syrup used in this study was purchased from Abidi Company, which contains 10 mg of active substance per 10 cc. Usual consumption is 10 doses per day. In the control group, only a drop of iron is given to BHS children for 3 months each morning after breakfast
Main outcome variables
The number of Breath Holding Spells in a month

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161230031668N3**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-29, 1397/07/07**
Update count: **0**
Registration date
2018-09-29, 1397/07/07

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-10, 1397/03/20
Expected recruitment end date
2018-12-11, 1397/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effect of Fluoxetine on Breath Holding Spells in Children who refer to Ghaem hospital of Mashhad

Public title
Study the effect of Fluoxetine on Breath Holding Spells
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The frequency of Breath Holding Spells includes cyanootic or pallid at least every 2 weeks, once or more
Normal EKG Parental consent

Exclusion criteria:

Age
From **6 months** old to **30 months** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using a sealed envelope

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
Ethics committee of Mashhad University of Medical Sciences

Street address
Ghoreishi building, Daneshgah AVE

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Approval date
2018-06-09, 1397/03/19

Ethics committee reference number
IR.MUMS.fm.REC.1397.379

Health conditions studied

1

Description of health condition studied
Breath Holding Spells

ICD-10 code
R06.89

ICD-10 code description
Other abnormalities of breathing

Primary outcomes

1

Description
The number of Breath Holding Spells in a month

Timepoint
At the beginning of the study (before the intervention) and 3 months after the start of the consumtion

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: BHS Children are given 1 or 2 CCfluoxetine syrup with iron drop for 3 month each morning after breakfast . The fluoxetine syrup used in this study was purchased from Abidi Company, which contains 10 mg of active substance per 10 cc. Usual consumption is 10 doses per day.

Category
Treatment - Drugs

2

Description
Control group: In the control group, only a drop of iron is given to BHS children for 3 months each morning after breakfast.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Farah Ashrafzadeh

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Ahmad abad AVE, Ghaem hospital

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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
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Person responsible for updating data

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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

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

No - There is not 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