

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

2018-09-29, 1397/07/07

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

Registrant information

Name

farah ashrafzadeh

Name of organization / entity

Mashhad University of Medical Seinces

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 4834

Email address

ashrafzadehf@mums.ac.ir

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 consumption

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

Street address
Ahmad abad AVE, Ghaem hospital

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Phone
+98 51 3801 2753

Email
ashrafzadehf@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

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Email

ramresearch@mums.ac.ir

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**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Farzadfard

Position

Non-faculty specialist

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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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