Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of risperidone in the treatment of breath-holding attack in infants and children at neurology clinic of children’s medical center

Protocol summary

Study aim
Efficacy of risperidone in the treatment of breath-holding attack in infants and children at neurology clinic of children’s medical center
Design
This clinical trial, consist of one Intervention with 30 data sample and the phase of the study is 2.
Settings and conduct
Infants and Children 1 to 7 years of age referred to Neuroscience Hospital of Children Medical Center for treatment if they are diagnosed and eligible for the study, are treated with risperidone and are followed monthly. Finally, they are evaluated at the end of 12 weeks.
Participants/Inclusion and exclusion criteria
Entry conditions: having experienced one or more breath-holding attack Exit conditions: Patients with a history of seizure
Intervention groups
To the subjects studied by age, under two years, a quarter of risperidone 1 mg tablets and children over two years of age, one-half of risperidone 1 mg tablets, it is given once a day for three months.
Main outcome variables
Number of breath-holding attacks; breath-holding grade

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200203046350N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **retrospective**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**
Registration date
2020-12-12, 1399/09/22

Registrant information
Name
Alireza Abdi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6147 2751
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alireza.abdi129@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-14, 1399/04/24
Expected recruitment end date
2020-10-15, 1399/07/24
Actual recruitment start date
2020-07-14, 1399/04/24
Actual recruitment end date
2020-10-15, 1399/07/24
Trial completion date
2020-10-15, 1399/07/24

Scientific title
Efficacy of risperidone in the treatment of breath-holding attack in infants and children at neurology clinic of children’s medical center

Public title
Effect of risperidone in breath-holding
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
having experienced one or more breath-holding attack
Exclusion criteria:
Patients with a history of seizure

Age
From **1 year** old to **7 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
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 Tehran University of Medical Sciences
Street address
District 6, Keshavarz Boulevard and Ghods St. crossing. Main Office of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-07-12, 1399/04/22
Ethics committee reference number
IR.TUMS.CHMC.REC.1399.075

Health conditions studied

1

Description of health condition studied
breath-holding
ICD-10 code
R06.89
ICD-10 code description
Other abnormalities of breathing

Primary outcomes

1

Description
number of breath-holding attack
Timepoint
Before treatment to three months after treatment
Method of measurement
Number of breath-holding attacks based on observation

2

Description
breath holding grade
Timepoint
Before treatment to three months after treatment
Method of measurement
breath-holding grade based on observation

Secondary outcomes

empty

Intervention groups

1

Description
Patients with a diagnosis of breath-holding attacks and over one year of age with a grade of two or three, treated with low-dose risperidone (one-quarter pill for children under two years of age and one-half pill of 1 mg-risperidone pill for children over two years of age) once daily, for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
Alireza Abdi
Street address
No. 62, Mohammad Gharib Street, Keshavarz Blvd.
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cmcpr@tums.ac.ir
Web page address
http://chmc.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. mohammad ali sahraeyan
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District 6, Keshavarz Boulevard and Ghods St. crossing. Main Office of Tehran University of Medical Sciences
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Email
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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Alireza Abdi
Position
Pediatric Neurologist Assistant
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
All the information about outcomes will be published
When the data will become available and for how long
6-12 months after publication
To whom data/document is available
Researcher of the academic institute
Under which criteria data/document could be used
The data of our study will be accessible by other researchers, for ducting meta-analysis
From where data/document is obtainable
No decision is made yet.
What processes are involved for a request to access data/document
The researchers should explain the aims of their study. The request is assessed by our team, and if we agree to the request, the request will be emailed.
Comments
No further explanation