

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of efficacy evaluation of Ritalin alone and Ritalin with supplement of ferrous sulfate on improvement of hyperactivity and inattention symptoms of non-iron deficient children with attention-deficit/hyperactivity disorder (ADHD)

Protocol summary

Summary

This study will be done to answer this question that whether or not Ritalin with supplement of ferrous sulfate treatment is more efficient than Ritalin alone in reduction of hyperactivity and inattention symptoms of children with attention-deficit/hyperactivity disorder (ADHD) and without iron deficiency. In a single blind clinical trial, sixty 6-11 year old children with ADHD and without iron deficiency (serum hemoglobin, iron and ferritin levels in normal limits) who would be referred to Pediatric Neurology Clinic of Shahid Sadoughi Hospital, Yazd, Iran will be distributed randomly into two groups. In group I, 20 mg/day of Ritalin and in group II, 20 mg/day of Ritalin and 2mg/kg/day of ferrous sulfate will be given. The drugs will be continued for three months and the children will be followed up monthly for three consecutive months. Primary outcomes include ADHD diagnostic rating scale and the parent Conner rating scales that will be compared before and after three months of treatment. Secondary outcomes include more than 50% of reduction in ADHD diagnostic rating scale and clinical side effects. The trial uses computer generated equal simple randomization by random numbers and data collectors, outcome assessors and data analysts are kept blinded to the allocation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512262639N17**

Registration date: **2016-04-16, 1395/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-16, 1395/01/28

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2015-04-23, 1394/02/03

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of efficacy evaluation of Ritalin alone and Ritalin with supplement of ferrous sulfate on improvement of hyperactivity and inattention symptoms of non-iron deficient children with attention-

deficit/hyperactivity disorder (ADHD)	۱۷/۱/۱۷۶۲/ پ
Public title Evaluation of efficacy of Ritalin and ferrous sulfate in non-iron deficient children with attention-deficit/hyperactivity disorder (ADHD) Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Age range of 6-11 years; having ADHD based DSM-IV criteria; having at least score of 20 in ADHD diagnostic rating scale via parent interview; No iron deficiency (serum hemoglobin, iron and ferritin levels in normal limits); Not receiving iron combinations within the past two months; No use of any ADHD therapy Exclusion criteria: Acute or chronic medical disorders; epilepsy; tic; severe birth asphyxia; severe neonatal jaundice; vision problems; hearing disorders; other psychiatric disorders; irregular drugs usage; discontinuation of iron usage for more than one week Age From 6 years old to 11 years old Gender Both Phase 2-3 Groups that have been masked <i>No information</i> Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized Randomization description Blinding (investigator's opinion) Single blinded Blinding description Placebo Not used Assignment Parallel Other design features	Health conditions studied 1 Description of health condition studied Attention-deficit/hyperactivity disorder ICD-10 code F90.0 ICD-10 code description Disturbance of activity and attention Primary outcomes 1 Description ADHD diagnostic rating scale Timepoint Before and three months after treatment Method of measurement Parent interview 2 Description Parent Conner rating scales Timepoint Before and three months after treatment Method of measurement Parent interview Secondary outcomes 1 Description Efficacy in more than 50% of reduction in ADHD diagnostic rating scale Timepoint Three months after treatment Method of measurement Parent interview 2 Description Clinical side effects Timepoint Monthly until three months after treatment Method of measurement Asking from parents
Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran Street address Central building of university, Bahonar square City Yazd Postal code Approval date 2015-03-17, 1393/12/26 Ethics committee reference number	Intervention groups 1 Description Tablet of 10 mg of Ritalin from Novartis Co, Switzerland in dosage of 20 mg/day divided in two doses and tablet

of 50 mg ferrous sulfate from Daroupakhsh Co, Iran in dosage of 2 mg/kg/day single dose for three months

Category

Treatment - Drugs

2

Description

Tablet of ten mg of Ritalin from Novartis Co, Switzerland in dosage of 20 mg/day divided in two dose for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Neurology Clinic of Shahid Sadoughi Hospital, Yazd, Iran

Full name of responsible person

Dr. Raziieh Fallah

Street address

Shahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr. Amirhoshang Mehrparvar

Street address

Central building of university, Bahonar Square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr. Raziieh Fallah

Position

Pediatric neurologist, associate professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty