

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Studying the effect of Livergol in children with attention deficit hyperactivity disorder

Protocol summary

Study aim

Assessment of efficacy of Livergol tablets on ADHD symptoms

Design

Randomized Phase 2 clinical trial, on 40 patients, for randomization the www.random.org website was utilized.

Settings and conduct

Forty patients with attention deficit hyperactivity disorder referred to the children's psychiatric clinic of Imam Khomeini Hospital will be randomly divided into two groups. Both groups will receive standard treatment (Ritalin). The intervention group will receive Livergel 70 mg tablets daily for 60 days, and the control group will receive a placebo tablet once a day for 60 days. Connors questionnaire will be taken at the beginning and end of the study. Patients and therapists will be blinded to the assignment group. Medicine tablets and placebo tablets are prepared in the same package and marked with a unique code. Community Verified icon

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 6-15 years old Receiving written informed consent from patients Diagnosis of ADHD is based on K_SADS by the Psychiatrist No other psychiatric disorders Lack of mental retardation Not having a history of heart disease Not having history of seizure No drug allergy history Exclusion criteria: Children with other psychiatric disorders Children with an allergy or previous side effects to Livergol

Intervention groups

Intervention group: patients will receive Ritalin and one tablet of livergol 70 mg daily for 60 days. Control group: patients will receive Ritalin and one placebo tablet daily for 60 days.

Main outcome variables

the Connors ADHD rating scales

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N22**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 1889

Email address

r_abrishami@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of Livergol in children with attention

deficit hyperactivity disorder

Public title
efficacy evaluation of livergol in children with attention deficit hyperactivity disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age between 6-15 years old receiving written informed consent from patients diagnosis of ADHD is based on K_SADS by the Psychiatrist
Exclusion criteria:
children with other psychiatric disorders children with an allergy or previous side effects to Livergol Drug allergies History of seizures Pregnancy Lactation

Age
From **6 years** old to **15 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
At the start of the study and after 60 days the Conners ADHD rating scale will be used

Randomization (investigator's opinion)
Randomized

Randomization description
two groups of 20 patients were made using simple randomization method, based on Random sequence Generator via www.random.org website. For random allocation concealment, the method of opaque sealed envelopes with random sequence was used. Patients were allocated in one of two groups based on their entry sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and Psychiatric will be blind about allocation

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of islamic Azad university of pharmaceutical sciences

Street address

No 99, the first of yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Province

Tehran

Postal code

۱۹۳۹۵۶۴۶۶

Approval date

2023-05-03, 1402/02/13

Ethics committee reference number

IR.IAU.PS.REC.1402.054

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

the Conners ADHD rating scales

Timepoint

At the entry and day 60

Method of measurement

the Conners ADHD rating scales

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will receive Ritalin and one tablet of livergol 70 mg daily for 60 days

Category

Treatment - Drugs

2

Description

Control group: patients will receive Ritalin and one placebo tablet daily for 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital

Full name of responsible person

Mahla Tajabadi pour

Street address

At the end of Keshavarz Blv.

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Province

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Postal code

1419733141

Phone

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Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoud Parsania

Street address

Building of Islamic abad university of medical
branch,Gol Yakh ave, Pa barja st, Shariari st.

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mparsania@iautmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Efat panah

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Tehran University of Medical Sciences,Enghelab
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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahla Tajabadi pour

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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

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