

Zinc sulfate as an adjunct to methylphenidate for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children: a double blind and randomised trial

Submission date 22/02/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/02/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2007	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Shahin Akhondzadeh

Contact details

Roozbeh Psychiatric Hospital
Tehran University of Medical Sciences
South Kargar Street
Tehran
Iran
13337
s.akhond@sina.tums.ac.ir

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Roozbeh Trial

Study information

Scientific Title

Acronym

Zinc ADHD Trial

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD)

Interventions

Patients were randomised to methylphenidate 1 mg/kg/day + zinc sulfate 55 mg/day (with approximately 15 mg zinc element) (group 1) and methylphenidate 1 mg/kg/day + placebo (sucrose 55 mg) (group 2) for a 6 week double blind clinical trial. The principal measure of the outcome was the Teacher and Parent ADHD Rating Scale. Patients were assessed by a child psychiatrist at baseline, 14, 28 and 42 days after the medication started.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methylphenidate, zinc sulphate

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2002

Completion date

01/10/2003

Eligibility**Key inclusion criteria**

Subjects were 44 outpatient children (26 boys and 18 girls) between the ages of 5 - 11 (mean \pm SD was 7.88 ± 1.67) who clearly met the Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM IV) diagnostic criteria for attention-deficit hyperactivity disorder.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

44

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

01/10/2003

Locations**Countries of recruitment**

Iran

Study participating centre
Roozbeh Psychiatric Hospital
Tehran
Iran
13337

Sponsor information

Organisation
Tehran University of Medical Sciences (Iran)

Sponsor details
South Kargar Street
Tehran
Iran
13337
s.akhond@sina.tums.ac.ir

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/01c4pz451>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tehran University of Medical Sciences (Iran)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	08/04/2004		Yes	No