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	Recruitment status No longer recruiting	Prospectively registered	
22/02/2004		☐ Protocol	
Registration date 23/02/2004	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 24/08/2007	Condition category Mental and Behavioural Disorders	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

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 \pm 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

https://ror.org/01c4pz451

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Tehran University of Medical Sciences (Iran)

Results and Publications

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