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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

Registration date
23/02/2004

Overall study status
Completed

Last Edited
24/08/2007

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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

01/10/2003

Eligibility

Key inclusion criteria
Subjects were 44 outpatient children (26 boys and 18 girls) between the ages of 5 - 11 (mean ± 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

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