ISRCTN10628149 https://doi.org/10.1186/ISRCTN10628149

A randomised, double-blind, placebo-controlled clinical trial of a Compound Herbal Preparation (CHP) in the treatment of children with Attention-Deficit Hyperactivity Disorder (ADHD)

Submission date
22/10/2007

Registration date
30/10/2007

Last Edited
18/03/2010

Recruitment status
No longer recruiting

Overall study status
Completed

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

Contact name
Ms Aliza Adar Levine

Contact details
108 Nachliel
DnModin
Israel
71938

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
To evaluate whether a Compound Herbal Preparation (CHP) improves attention, impulse control, and cognitive functioning in children with Attention-Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive type (ADHD-PI) and Predominantly Hyperactive-Impulsive type (ADHD-HI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Sheba Medical Center Ethical Review Board/Israel Ministry of Health in October 2004.

Study design
A randomised, double-blind, placebo controlled trial, conducted at a single-centre (the Sheba Medical Centre).

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention-Deficit Hyperactivity Disorder (ADHD)

Interventions
Following assessment and diagnosis by a paediatric psychiatrist, using DSM-IV criteria, participants were randomly assigned (in 2:1 ratio) to a treatment group (n = 80) and a control group (n = 40), each comprising combined ADHD-PI, and ADHD-HI types. Participants were given a diagnosis-appropriate CHP (n = 80), or a placebo (n = 40) over a period of 4 months.

The "Compound Herbal Preparation" (CHP):
The CHP being evaluated consists of a blend of nutritive, food-grade botanicals (as approved by the Israeli Health Ministry) and prepared as a dilute ethanol extract. The Compound Herbal Preparations (CHP/CHP-H) under study are registered under the name Rikuzit ("Rikuzit"®/" Rikuzit-H"® in Israel - Hebrew for concentration), and Nurture & Clarity ("Nurture & Clarity"®/" Nurture & Clarity-H"®) internationally, and are at this time only available to Etz-HaChayim Clinic patients undergoing therapy. At this time, the CHP is not connected with any pharmaceutical or manufacturing company.

A dose of 3 ml CHP or placebo was to be taken by the participants 3 times daily, before meals, diluted in 50 - 60 ml water. The CHP or placebo was home administered by parents, and proceeded with ease throughout the study. Parents were instructed how to prepare (dilute in water) the daily dosage for the entire day. The morning, afternoon, and evening doses were administered at home before breakfast, lunch, and dinner. Alternatively, the noon/afternoon dose was taken at school.

Follow up continued for 6 months after the trial finished. All children who had received the placebo during the trial, were offered the CHP, for a period of 6 months free of charge, and subsequently monitored.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Compound Herbal Preparation (CHP)

Primary outcome(s)
Attention, cognitive function, and impulse control, were assessed before and after the treatment period by the 4 subscales of the Test of Variables of Attention (TOVA), as well as overall score:
1. Standard omission score
2. Standard commission score
3. Response time
4. Variability

A specialised paediatric psychiatrist administered the pre-treatment TOVA. Upon completion of the 4-month participation period, each subject was reevaluated using the TOVA, with the tester, a psychology student, who was blinded as to treatment status. The two ADHD groups were pooled in analysis.

Key secondary outcome(s))
Detailed questionnaires, designed for the study, monitored for side effects and general state of health, and included possible adverse effects such as insomnia, stomach aches, pains, nightmares, or anxiety; as well as an evaluation of compliance with the three daily doses. Each participant and his/her parents, participated in individual meetings at 3 - 4 week intervals where the questionnaires were completed, and evaluated. Additionally, the paediatric psychiatrist conducted assessment interviews with the each participant and his/her parents twice during the trial period: midway through and at the conclusion of the trial. The questionnaires served to assess the presence of side effects, not attention or cognitive function.

Completion date
20/03/2006

Eligibility

Key inclusion criteria
1. One hundred and twenty children, aged 6 - 12 years
2. Recruited from the Sheba Medical Center Clinic for Paediatric Behavioural Disorders
3. No history of prior treatment for ADHD
4. Diagnosed with ADHD-PI or ADHD-H by a specialised paediatric psychiatrist, based on Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria and assessment interviews with participants and their parents
5. Children meeting the DSM-IV criteria for inclusion in the study were evaluated with the Test of Variables of Attention (TOVA). Inclusion required a standard score of below 85 on at least one of the TOVA subscales

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Medical conditions, other than ADHD, causing inattention and hyperactivity (i.e., anaemia, hypoglycaemia, thyroid disorders, etc.)
2. A standard score of over 85 on all of the TOVA (Test of Variables of Attention) subscales

Date of first enrolment
10/12/2004

Date of final enrolment
20/03/2006

Locations

Countries of recruitment
Israel

Study participating centre
108 Nachliel
DnModin
Israel
71938

Sponsor information

Organisation
Etz-HaChayim Clinic (Israel)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Etz-HaChayim Clinic (Israel)

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	01/11/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes