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Benefits of polyunsaturated fatty acid (PUFA) supplementation in therapy of children and teenagers with Aspergers Syndrome

Submission date
11/05/2012

Recruitment status
No longer recruiting

Registration date
27/09/2012

Overall study status
Completed

Last Edited
06/06/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Aspergers syndrome is a developmental disorder which is often classified with a group of related conditions known as autistic spectrum disorders. Individuals with the disorder have average or above average intelligence and a well-developed speaking ability. Nevertheless, their social and communication skills are seriously affected, which leads to social isolation. The common symptoms of Aspergers syndrome include obsessive adherence to routines, excessive passion in a single and narrow subject or topic, rhythmic and intonation problems of language, delayed motor skills and impaired social communication, interaction and imagination skills. Although certain drugs are given to treat anxiety, depression and aggression co-existing with this disorder, there is no known curative drug for the main symptoms of Aspergers syndrome. Therefore, the mainstay management remains social skill training and behavior, occupational and speech therapies, and support and management training for parents. The long-chain polyunsatuated fatty acids (PUFAs) are vital components of the brain cell membranes and have been shown to influence neurological functions. There is evidence of insufficiency and imbalance of PUFA in persons with attention deficit hyperactivity disorder (ADHD), depression and autism spectrum disorders. The aim of this study is to investigate the benefits of PUFA in Polish children and adolescents with Aspergers syndrome.

Who can participate?
Fifty children and adolescents, aged 6 to 19 years, with normal intelligence index and communication ability and diagnosed with Aspergers syndrome and autism

What does the study involve?
The participants will be randomly allocated to be given either polyunsaturated fatty acid (PUFA) capsules or placebo (dummy) capsules for 3 months. After this period the participants who took the placebo tablets will take PUFA tablets for another 3 months.

What are the possible benefits and risks of participating?
Participants may experience an improvement in their clinical symptoms. PUFAs are nutrients commonly found in the diet. Hence, PUFAs do not present any risk to the participants.

Where is the study run from?
Indywidualna Specjalistyczna Praktyka Lekarska w Miejscu Wezwania (Poland).

When is the study starting and how long is it expected to run for?
The study started in October 2010 and is anticipated to be completed in August 2012.

Who is funding the study?
Vifor Pharma Ltd (Switzerland).

Who is the main contact?
Dr Beata Joanna Kozielec

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EQZ2007101

Study information

Scientific Title
Benefits of PUFA supplementation in therapy of children and teenagers with Aspergers Syndrome pilot study

Acronym
PUFA AS

Study objectives
In this randomized double-blinded, placebo-controlled study researchers will observe expected changes in the behaviour of children witha diagnosis of Aspergers Syndrome. The primary goal

of this trial is to evaluate the benefits of diet supplementation with PUFA in children with Aspergers Syndrome and 'well functioning' autism (with good speaking and normal intellectual abilities). The secondary goal is to evaluate the impact of PUFA supplementation with relation to initial parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Committee of the Institute of Mother and Child, Warsaw, Poland, 21/11/2008, ref:19 /2008

Study design
Double-blind randomized placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Asperger's syndrome

Interventions
Post randomization, the patients will be receive polyunsaturated fatty acid (n=25) or placebo (n=25) capsules for 3 months. This will be followed by a switch over of the placebo group to PUFA and further intervention for another 3 months.

Clinical symptoms and blood fatty acid status will be assessed at baseline and at two time points (3 and 6 months) during the intervention period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Polyunsaturated fatty acids (PUFA)

Primary outcome measure
1. To evaluate the possible benefits of PUFA supplementation in patients with Aspergers syndrome and autistic 'well functioning' children and teenagers with normal intelligence index and well-developed speaking abilities.
2. Changes in the core clinical symptoms pertaining to behavior and learning will be assessed by Conners Parent Rating Scales, psychiatric examination and questionnaire of symptoms, discussion with parents, based on ICD-10, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV), Australian Scale for Aspergers Syndrome of M.S. Garnett and A.J. Atwood, Asperger Syndrome Diagnostic Interview (ASDI) developed by the investigator.

Secondary outcome measures
To prepare initial indications to supplement subjects with Aspergers syndrome and autistic 'well functioning' children and teenagers with PUFA, based on psychiatric and psychological evaluation, and blood tests.

Overall study start date
01/01/2011

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Diagnosis of Aspergers syndrome according to ICD-10 (normal IQ)
2. Age 6 19 years

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients meeting at least one of below mentioned criteria (in the past or currently) will be excluded from participation in the study:
1. Bipolar disease
2. Psychotic disorders

3. Immunological disorders
4. Administration of PUFA or other fat supplements (e.g. lecithin) during last 3 months
5. Body mass index (BMI) lower than 18
6. Convulsions in the history (excluding high temperature convulsions)
7. Administration of epileptic drugs currently or in the past
8. Administration of alcohol or narcotic drugs during the last 3 months
9. Blood hypertension
10. Hyper- or hypothyroidism
11. Diabetes or glucose intolerance
12. Hyperlipidemia
13. Clotting abnormalities
14. Other acute or chronic diseases currently or in the past

Date of first enrolment
01/01/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Poland

Study participating centre
Pelikanów 2d/8
Piaseczno
Poland
05-500

Sponsor information

Organisation
Indywidualna Specjalistyczna Praktyka Lekarska w Miejscu Wezwania (Poland)

Sponsor details
c/o Dr Beata Joanna Kozielec
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Piaseczno
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Vifor AG (Switzerland)

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