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The effect of hyperbaric oxygen therapy in autism spectrum disorder

Submission date
09/10/2011

Recruitment status
No longer recruiting

Registration date
18/11/2011

Overall study status
Completed

Last Edited
02/08/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a condition where the main features are impairments in social interaction, difficulty with communication, and restrictive and repetitive behaviors. Hyperbaric oxygen therapy involves inhaling up to 100% oxygen at a pressure greater than one atmosphere (atm) in a pressurized chamber. The aim of this study is to test the effectiveness of hyperbaric oxygen therapy on the symptoms of ASD.

Who can participate?
Children aged 3-18 with Autism Spectrum Disorder (ASD)

What does the study involve?
Participating children are re-diagnosed by a qualified psychologist and aspects of their behavior and IQ are tested. Participants provide blood samples and undergo a scan before the start of the treatment. Participants are randomly allocated into two groups. One group follows a gluten and casein free diet supervised by a dietician for 4 months before the hyperbaric oxygen sessions. The other group receives no dietary preparation. All participants have 40 1-hour sessions of hyperbaric oxygen therapy at 2 ATA pressure at a rate of once a day for 8 weeks. There are no treatments or tests for 4 weeks after that, then participants have another 40 1-hour sessions at 1 ATA pressure at a rate of once a day for 8 weeks. There are no treatments or tests for 4 weeks after that.

What are the possible benefits and risks of participating?
The possible benefits are improvements in ASD symptoms and signs, which we are testing in our study. Participants may experience confinement anxiety and ear discomfort.

Where is the study run from?
King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2012 to January 2014

Who is funding the study?
King Abdulaziz City for Science and Technology (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Study the effectiveness of Hyperbaric Oxygen Therapy (HBOT) in Autism Spectrum Disorder (ASD): a randomized double-blind cross-over study

Acronym
HBOT

Study objectives
1. To determine the efficacy of HBOT on symptoms of ASD
2. To determine the effects of HBOT on oxidative stress markers, inflammatory biomarkers and immunological biomarkers in autistic children

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized double-blind cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions
1. This project will be conducted on 32 ASD children between 6 and 12 years of age
2. Written informed consent will be obtained from each childs parent(s) prior to starting HBOT.
3. Each child will be re-diagnosed by a qualified psychologist using Autism Diagnostic Observation Schedule (ADOS), Childhood Autism Rating Scale (CARS 2) and the several aspects of their behavior and IQ for each candidate will be tested using Social Responsiveness Scale (SRS), Childrens Communication Checklist (CCC) and Aberrant Behavior Checklist Community (ABC-C), Stanford Binet Intelligence Scale
4. All ASD candidates with one of their parent will be screened according to HBOT criteria by
4.1. ENT specialist
4.2. Pediatrician
4.3. HBOT specialist
5. Blood samples of each candidate will be taken for testing of oxidative stress, inflammatory and immunological biomarkers
6. Single Photon Emission Computed Tomography (SECT) for ASD candidates before the session of HBOT and at the end of the project
7. ASD candidates will be divided into the following groups:
7.1. Group 1 No dietary preparation prior to HBOT session
7.2. Group 2 Dietary preparation (gluten & casein free diet supervised by a Dietician for four months prior to HBOT session
8. All candidates will have 40 sessions for 1 hour of HBOT at 1 or 2 atmospheres absolute (ATA) and 100% oxygen (after adjustment for the pressure effect) every day over a 4-5 months period

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
1. Behavioral psychological parameters measure
1.1. Autism Diagnostic Observation Schedule (ADOS)
1.2. Childhood Autism Rating Scale (CARS 2)
2. The several aspects of their behavior and IQ for each candidate will be tested using
2.1. Social Responsiveness Scale (SRS)
2.2. Childrens Communication Checklist (CCC)

2.3. Aberrant Behavior Checklist Community (ABC-C)
2.4. Stanford Binet Intelligence Scale
2.5. Oxidative stress biomarkers (superoxide dismutase, gluthathione peroxidase, vit E, vit C)
2.6. Inflammatory biomarkers (IL-2, IL-7, IL-10)
2.7. Immunological biomarkers (IgG, IgA, anti-Myelin basic protein IgG, anti-ribosomal IgG , anti-ganglioside IgG)

Key secondary outcome(s))
Improvement in communication, social and speech, reflected on academic level

Completion date
01/01/2014

Eligibility

Key inclusion criteria
Children with ASD (Autism spectrum disorders) aged between 6 and 12

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
The following are the contraindications for the use of HBOT:
1. Pneumothorax
2. Previous chest surgery
3. Any lung disease
4. Viral infections
5. Recent (within the previous 2 months) middle ear surgery
6. Optic neuritis
7. Seizure disorders
8. Congenital spherocytosis
9. Psychiatric problems, especially claustrophobia
10. Recent dental procedures
11. Deafness or ringing noises in ears
12. Severe or frequent headaches

13. Migraine
14. Fainting or blackouts
15. Convulsions, fits or epilepsy
16. Concussion or head injury
17. Heart diseases
18. Pregnancy

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud University
Riyadh
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Sponsor information

Organisation
King Abdulaziz City for Science and Technology (Saudi Arabia)

ROR
https://ror.org/05tdz6m39

Funder(s)

Funder type
University/education

Funder Name
King Abdul Aziz City for Science and Technology, King Saud University (Saudi Arabia)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes