

# The effect of hyperbaric oxygen therapy in autism spectrum disorder

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| <b>Submission date</b><br>09/10/2011   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>18/11/2011 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>02/08/2016       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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?  
Prof. Laila Y. AL-ayadhi  
ayadh2@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Laila AL-Ayadhi

**Contact details**  
Director of KSU-Autism Research and Treatment center (99)  
Supervisor of Shaik AL-Amodi Autism Research Chair  
Department of physiology (29)  
Faculty of Medicine  
King Saud University  
PO Box 2925  
Riyadh  
Saudi Arabia  
11461  
+966 (0)1 467 0848  
ayadh2@gmail.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Hospital

**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**

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 child's 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), Children's 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 (SPECT) 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 measure**

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, glutathione 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)

## **Secondary outcome measures**

Improvement in communication, social and speech, reflected on academic level

## **Overall study start date**

01/01/2012

## **Completion date**

01/01/2014

# **Eligibility**

## **Key inclusion criteria**

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

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

6 Years

## **Upper age limit**

12 Years

**Sex**

Both

**Target number of participants**

32

**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

Saudi Arabia

11461

**Sponsor information**

**Organisation**

King Abdulaziz City for Science and Technology (Saudi Arabia)

**Sponsor details**

King Abdulaziz City for Science and Technology Kingdom of Saudi Arabia

P.O Box 6086

Riyadh

Saudi Arabia

11461

**Sponsor type**

University/education

**Website**

<http://www.kacst.edu.sa>

**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****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