MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient

INSTITUTE: National Institute of Mental Health

STUDY NUMBER: PRINCIPAL INVESTIGATOR:

STUDY TITLE: Effects of Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder: A functional magnetic resonance study

Latest IRB Review: New Protocol
Latest Amendment Approved:N/A

Standard – Parent of Healthy Child

INTRODUCTION

We invite you and your child to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive study-related care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You will receive no direct benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Introduction:

Your child is invited to volunteer in an outpatient research study on the effects of a single dose of dextroamphetamine on brain activation patterns in healthy children and children with ADHD and hyperactive children. Dextroamphetamine is a psychostimulant that has been approved by the FDA for the treatment of ADHD in both children and adolescents. Your child has been asked to participate because he/she has no diagnosis of ADHD or of any other psychiatric disorder.

Purpose of the Study:

The purpose of this study is to:

- Compare brain activation patterns in both healthy children and children with ADHD
- Compare the effects of a single dose of dextroamphetamine on brain activation patterns in healthy children and children with ADHD
- Examine whether brain activation patterns associated with ADHD are caused by the symptoms of ADHD or genes that affect brain patterns

Confidentiality:

The Federal Privacy Act protects the confidentiality of your child's NIH medical records. However, you should know that the Act allows release of some information from medical records without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

Although all information will be kept confidential, if, during the course of the study, there is any evidence that your child has been abused, we are obligated by law to report it to the appropriate authorities. With regard to information that your child gives to us, we will follow the usual standard of practice among child psychiatrists. That is, we will respect your child's right to confidentiality, but we must also protect their safety, and so we will share with you and your children's physician information concerning behavior or thoughts that, in our judgment, pose a serious risk to him/herself or others.

Randomization & Double-Blind:

This study is a randomized, double-blind experiment. During this study, two different pills (a placebo and a dextroamphetamine) will be given to your child in a random order. That means that some children will receive the placebo during their first imaging visit and some will receive the dextroamphetamine first. All children in this study will receive each of these two pills once. Neither the doctors nor you will know which treatment your child has been given during the imaging sessions until the study is over. **If a medicine makes your child feel ill, the doctor can find out which medication your child received.**

Duration and Study Overview:

1. Psychiatric assessment: Your child's eligibility will be determined through a series of screening examinations. These include tests that will evaluate your child's cognitive abilities, teacher and parent ratings, and an interview that will screen for ADHD as well as other psychiatric conditions. If other significant conditions are found they may disqualify your child from this study. If this is the case, your child will be paid for participating in the screening process.
2. Imaging Sessions: After your initial interviews and before the first session, your child will complete a training session in an fMRI simulator. This training will allow your child to begin to master the tasks that he/she will complete during the sessions and to become accustomed to the sounds and environment of the fMRI machine itself. Then, your child will be scheduled for two imaging sessions at NIH. During these sessions, we will take pictures of your child's brain activity while he/she completes attention and memory tasks in an fMRI machine. In these tasks your child watches a computer screen and responds by pressing a button with his/her finger when the correct signal is seen. Before these sessions begin your child will be given either the placebo or dextroamphetamine medicine. After your child completes the testing in the MRI machine during each session, we will ask him/her to complete a questionnaire that will measure your child's motivation to complete the experimental tasks. This survey will ask your child to rate how your child feels about the tasks (for example, boring, interesting, tiring, difficult). We will ask your child to complete this survey after both imaging sessions.

Qualifications to Participate/Exclusion:

Some of the requirements to be in this study are:

- Age between 9 and 18.
- No current psychiatric or medical conditions
- A WISC-R or WISC-III total IQ score of 80 or above.

A child is excluded if:

- He/she has any significant medical or neurological disorders or major psychiatric condition
- Any member of his/her immediate family has ADHD
- He/she takes any medications that cannot be discontinued for this study.
- He/she has any type of metal objects (for example, pins or rods) in his/her body. These objects interact with the magnetic field created by the fMRI machine and could endanger your child.
- Weight is less than 25 kg.

Risks, Inconveniences and Discomforts:

1. Psychiatric Assessment – The screening for this study is a series of phone and face-to-face interviews that take about three hours. These have been conducted hundreds of times at NIH with no serious effects. If, however, your child becomes upset by any questions during the assessment, he/she can refuse further participation and the interview will be stopped. We will provide you with a phone number to contact if you have any questions about the interviews or any other part of the assessment process.
2. Single-dose dextroamphetamine – The most common side effects of the low single dose of amphetamine are loss of appetite and insomnia that last a few hours. When these effects are seen after dextroamphetamine treatment, they typically disappear in a few hours. There are a range of other possible side-effects associated with stimulant use including constipation, diarrhea, nausea, and confusion, but these have only very rarely been noted after a single low dose. In a previous NIMH study with 14 normal children, no bad

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effects were seen after administration of a similar single dose of dextroamphetamine except for mild loss of appetite and mild insomnia mentioned above. It has also been questioned whether exposure to stimulants may increase the chances for drug abuse later in life. Four studies have investigated this possibility and three have shown that there is no connection between stimulant therapy and an increased risk for drug abuse. Two of these studies, in fact, indicated that children with ADHD who were treated with stimulants had a lower risk for future drug abuse than those who were not medicated. Dextroamphetamine has been approved by the FDA for the treatment of ADHD in children and adolescents. Based on the NIH studies, the effects of a single-dose of oral dextroamphetamine are expected to fall within the range of experiences that your child could normally have during his/her childhood.

3. fMRI – The magnetic field and radio waves used for these types of scans are considered too weak to do any damage. While it is always difficult to prove the complete absence of any unwanted side effects, studies of possible side effects have revealed none. However, people are at risk of injury from MRI scans if they have metal objects in their bodies such as pacemakers, aneurysm clips (metal clips on the wall of a large artery), metallic prosthesis, cochlear implants, or shrapnel fragments. People with such metal implants should not receive an MRI scan, since the strong magnet of the fMRI machine may cause metal objects in a person's body to move, and this movement may cause tissue damage. We do not know for sure whether fMRI scans might have negative effects on unborn children, so we do not scan pregnant women, and all female subjects age 15 and above receive pregnancy tests on the day of the scanning to be sure that they are not pregnant.

People with a fear of tight spaces may become anxious during a MRI scan. In addition, the scanner does make loud noises. Your child will be given earplugs to wear to help decrease the noise. Your child can talk to the staff while he/she is in the scanner. If your child becomes uncomfortable and wants for the scanning session to stop, this will be done.

Occasionally, the MRI examination will detect something unexpected in your child's brain, such as a mass or other kind of abnormality. Sometimes such findings are of no consequence but nevertheless will require your child to undergo follow-up with his/her physician. Additional tests that may be required will be at your own expense. We will communicate any abnormal findings from the MRI study to you and, if you wish, to your child's physician. However, it is important to understand that NIH cannot treat or provide any additional tests for an incidentally detected problem. You will be responsible for further investigation of an additional problem if one is found. This represents a risk participating in the study, but it is also a potential benefit to your child if a serious illness is detected early.

Additional Protections for your child:

We are committed to the safety and well being of your child and we will keep in close communication with you about his/her progress through the evaluation process. In addition to the expertise of our clinical and research staff our program is provided with external sources of oversight and advocacy for your child's participation in our program.

1. You may withdraw your child at any time; or ask that the study or a specific aspect of the evaluation be stopped. Doing so will not jeopardize your child's care.

2. **Data and Safety Monitor – an independent physician may be chosen to oversee the study, to make sure that all precautions are made to keep the children participating in the study safe. Once this monitor is selected, you will be given his/her contact information.**

Women of Childbearing Years:
Females of childbearing years will be asked about their menstrual history and will have a pregnancy test prior to starting the study. Only females known not to be pregnant will be included.

Potential Benefits That May Accrue From the Study

Your child will not receive any direct clinical benefits from his/her participation in this study. Participation in this study will allow your child to learn about the process of clinical research and about fMRI technology. All children who participate in any part of this study will be financially compensated for their involvement. Some children are glad to be helping research that will help other children their age with attention and behavior problems.

By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Rapoport at 301-496-6081.

Alternative Treatments: N/A

Financial Compensation

Financial compensation for this study will be as follows:
Screening Session - $70
- 3 Hours
- K-SADS: 1 Inconvenience Unit (IU)
- Physical Exam: 1 IU
- WASI: 1 IU

Visit 1 - $250
- 4 Hours
- fMRI Session: 13 IU
- Placebo Treatment: 1 IU

Visit 2 - $250
- 4 Hours
- fMRI session: 13 IU
- Amphetamine Treatment: 1 IU

Total possible study compensation: $570

New Findings:

There might be risks involved that are currently unforeseeable. You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Voluntary Participation/Withdrawal:

Your child's participation is voluntary. You may refuse for your child to participate, or may discontinue your child's participation at any time without penalty.

The doctors on the research team have the right to stop your child's participation in the study at any time. This decision could be because he/she has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Judith L. Rapoport, M.D.; Building 10, Room 6N240, Telephone: 301-496-6081.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent	B. Parent's Permission for Minor Patient.
I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.	I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)
_____ _____ Signature of Adult Patient/Legal Representative Date	_____ _____ Signature of Parent(s)/Guardian Date

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

_____ _____

Signature of Parent(s)/Guardian Date

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM

Signature of Investigator	Date	Signature of Witness	Date