***Title*: Use of Amantadine in Treating Cognitive and Motor Impairments in Adolescents and Adults with Cerebral Palsy**

H*eakyung Kim, MD*
Columbia University Irving Medical Center, Department of Rehabilitation and Regenerative
AAAS1907
NCT04273737
INFORMED CONSENT FORM Version 12/16/2020

Principal Investigator: Heakyung Kim, MD
Columbia University Irving Medical Center
180 Fort Washington Ave
New York, NY 10032

Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAS1907
Principal Investigator: Heakyung Kim (hk2641)
IRB Protocol Title: Use of Amantadine in treating cognitive and motor impairments in adolescents and adults with cerebral palsy

General Information

Consent Number: CF-AACB2650
Participation Duration: 6 weeks
Anticipated Number of Subjects: 10
Research Purpose: We are doing a research study to find out whether a drug called Amantadine may be helpful for adolescents and adults with cerebral palsy. This drug was primarily developed and used to treat people with influenza. Research has shown Amantadine improves cognitive arousal and alertness in patients with traumatic brain injuries (TBI) and has also been shown to help with Parkinsonism. However, we do not know if it may be helpful for people with Cerebral Palsy. There have been no previous studies investigating the effects of Amantadine in the CP population. The aim of this study is to determine the effects of Amantadine in adolescents and adults with CP and to compare pre- and post-intervention outcomes related to the primary goal of improving cognitive function, focused on processing speed and attention span.

This consent form is written to address a research subject. If you are a parent providing consent for your child to participate in this research study, please read "you" in this consent form as "your child".

Information on Research

Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent form.

Study Procedures

If you choose to be part of this research study, you will be asked to take Amantadine twice a day for a period of 6 weeks. We will perform a number of cognitive/neurological and physical measurement tests before you start taking the drug, and again three and six weeks after you start taking the drug to get an idea of whether it may be helpful.

This study will consist of approximately 3 clinic visits over a period of 6 weeks.

The study will occur as follows:
-Initial visit
-Follow-up visit at 3 weeks
-Follow-up visit at 6 weeks

Initial Visit
At this visit, a baseline assessment of cognitive function, gross and fine motor function, and mood/psycho-social function will be conducted.

The following assessment tools will be used:
-Cognitive function: you will be taken through six different oral/written/visual tests
-Mood: PHQ-9 questionnaire, BRIEF-A
-Gross motor function: your balance will be assessed using the Berg Balance test, you will be asked to complete a 30-second Timed Up & Go, physical measurements of your range of motion and level of muscular spasticity
-Fine motor function: you will be taken through a test that will assess fine motor function

You will be given a diary to document your perceived effects of the medication throughout the 6 weeks.

At this initial visit, you will be introduced to the drug, its potential side-effects, and its prescribed doses that you will be asked to follow for the duration of the 6 weeks.

Follow-up visit at 3 and 6 weeks
At these follow-up visits, assessments of cognitive function, gross and fine motor function, and mood/psycho-social function will be conducted.

You can contact the study doctor at any time during the study. It is important that you share any medical problems you may have or new developments/medications with the study doctor.

Subject Responsibilities

As you are a study subject, you are responsible for ensuring that you follow the study directions and those of the study doctor. This includes returning promptly to the study doctors office for all necessary study follow-up visits, reporting any changes in your medications (over-the counter and prescription), and reporting any changes in how you feel to the study doctor.

If you experience any illness or discomfort during the study, you should notify the study doctor. The study doctor will then evaluate you to determine if you should continue the study.

Risks

Possible Side-Effects of Amantadine

The adverse reactions reported most frequently at the recommended dose of SYMMETREL (amantadine hydrochloride) (5-10%) are: nausea, dizziness (lightheadedness), and insomnia.

Less frequently (1-5%) reported adverse reactions are: depression, anxiety and irritability, hallucinations, confusion, anorexia, dry mouth, constipation, ataxia, livedo reticularis, peripheral edema, orthostatic hypotension, headache, somnolence, nervousness, dream abnormality, agitation, dry nose, diarrhea and fatigue.

Infrequently (0.1-1%) occurring adverse reactions are: congestive heart failure, psychosis, urinary retention, dyspnea, skin rash, vomiting, weakness, slurred speech, euphoria, thinking abnormality, amnesia, hyperkinesia, hypertension, decreased libido, and visual disturbance, including punctate subepithelial or other corneal opacity, corneal edema, decreased visual acuity, sensitivity to light, and optic nerve palsy.

Rare (less than 0.1%) occurring adverse reactions are: instances of convulsion, leukopenia, neutropenia, eczematoid dermatitis, oculogyric episodes, suicidal attempt, suicide, and suicidal ideation.

Loss of Confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Confidentiality section of this consent form.

Benefits

Will you benefit from being in this study?

The study treatment (i.e. Amantadine) may or may not help you. It is hoped that the information gained from the study will help in the future treatment of adults with Cerebral Palsy.

Alternative Procedures

What other options are there?

The alternative is to not participate in the study. You will still receive all necessary standard of care under Dr. Kim not associated with this study.

Confidentiality

What about confidentiality?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer, may occur, although it is highly unlikely.

Any research information that is shared with people outside of Columbia University Medical Center and New York Presbyterian
Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

All material will be kept under lock and key in the Principal Investigator's office in Harkness Pavilion. Only study personnel will have access to the study information. All study forms will be de-identified for confidentiality.
The following individuals and/or agencies will be able to look at and copy your research records:
- The investigator, study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board (IRB)
- The United States Food and Drug Administration (FDA) and/or the Office of Human Research (OHRP)

Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure; however we do not anticipate sharing any collected health information. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Dr. Heakyung Kim at 212-342-1395.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers may continue to use and disclose the information they have already collected. The study team will have access to your data for future use of research. Only members of the research team will have access to your de-identified data which
will remain in a password-protected encrypted database. Your data will be kept indefinitely as defined by law.

Research Related Injuries

What if I get hurt while I am on the study?

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. If this medical care is provided by NYPH or by a Columbia doctor, the study sponsor may pay these providers for any reasonable medical expenses to treat your injury. The study sponsor, however, is not offering to pay for medical expenses that are covered by your insurance provider or if your injury was not caused by the study drug/device or a study procedure.

Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Compensation

Will I be compensated?

Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the Amantadine drug after the termination of the study.

Additional Costs

What are the costs?

No added costs

Taking part in this study will not involve additional costs to you. All study drugs will be given free of charge by the funding sponsor. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

Voluntary Participation

Do I have to be in the study?

Voluntary Participation

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Additional Information

Additional Information

Use of Data/Specimens

We would like to store the data that you agreed to provide as part of this study and possibly use them for future research and/or publications. They will be stored in a locked filing cabinet in the researcher's office only accessible to this research team. Your data will be labeled with a code number that only the researchers on this study will be able to link to you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you have any further questions, please contact the study Doctor, Heakyung Kim at (212) 305-5337, or the study coordinator, Nancy Lee at (212) 305-9416.

If you have any questions about your rights as a subject, you may contact:

Institutional Review Board
Columbia University Medical Center
722 West 168th Street, 4th Floor
New York, NY 10032
Telephone: (212) 305-5883

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

Statement of Consent

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction.

I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Parent/Guardian

Print Name _____ Signature _____

Date _____

Study Subject

Print Name _____ Signature _____

Date _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date _____