Effects of Acthar on Recovery From Cognitive Relapses in MS

NCT02290444

Informed Consent Form

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Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Effects of Adrenocorticotropic Hormone (Acthar®) on Recovery from Cognitive Relapses in MS

Version Date: 12 June 2018

Investigator: Ralph Benedict PhD

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are either: 1) having an MS relapse and your doctor or nurse practitioner feels that you may benefit from Acthar (Adrenocorticotropic Hormone) treatment, or 2) your MS is stable and you are matched on demographic variables to a relapsing participant.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-323-0552. You may also contact the principle investigator, Dr. Ralph Benedict at 716-323-0556.You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?

The purpose of this study is to evaluate the effect of a medication called Acthar® (Adrenocorticotropic hormone**)** on people with multiple sclerosis (MS) who experience a relapse (exacerbation) that affects their cognition. The study drug is investigational in so far that its effect on cognition is unknown. This type of relapse may affect concentration, memory, or level of fatigue, symptoms that are in general less carefully evaluated as compared to the physical limitations that usually are much easier identified during an acute MS relapse.

How long will the research last?

We expect that you will be in this research study for 90 days.

How many people will be studied?

We will enroll 30 relapsing MS patients and 30 stable MS patients matched on demographic variables.

What happens if I say yes, I want to be in this research?

You will be asked to make a total of two (2) visits, approximately 90 days apart. Each visit will involve: a physical/neurological exam, neuro-performance testing, and self-report questionnaires. Each study visit is expected to take approximately 60 minutes.

During the first visit:

1) Your medical history and medications will be reviewed and you will be given a neurological examination, if one has not already been completed in the past 7 days.

2) You will complete a brief test of cognition.

3) If you meet the criteria required for the study and you wish to continue, you will complete a series of tests and questionnaires that measure your walking speed, dexterity, memory and thinking speed.

4) If you are in the treatment group (relapsing), you will be instructed on self-administration of Acthar®(Adrenocorticotropic Hormone**)** and receive your first dose. You will be given instructions on how much Acthar® to take and for how many days to take it at home. The study drug will be provided to you through the study. If you are stable and matched to another participant, there will be no changes in your treatment or clinical care.

5) You will be contacted 7 days, 30 days, and 90 days from your first visit and asked about changes in your medical status or medications.

At 90 days, you will return for the 60-minute follow-up visit where you will receive a neurological examination and complete the cognitive testing and questionnaires, again.

Some of the surveys have forms are to be completed by a person who knows you well, such as a spouse, adult child or a caregiver. If such a person is available and has agreed to help you participate in this study, that person will also provide information about you using the surveys and this will require about 15 minutes of their time. If that individual is not available in person, then with your permission, we will contact him/her by telephone.

By signing this consent, you are giving us permission to access the clinical data collected during your initial clinical visit and screening tests for eligibility to take Acthar (Adrenocorticotropic Hormone**)**.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be asked to provide informed consent and to complete study visits at days 0 and 90. If you are a relapsing patient you will be required to take the appropriate doses of Acthar (Adrenocorticotropic Hormone) in accordance with the study and your neurologist's recommendation.

What happens if I do not want to be in this research?

Participation in this study is voluntary. You may refuse to participate without penalty and such refusal will not prejudice future treatment at the Jacobs MS Center. If you choose to withdraw from the study, the data collected up to the time of withdrawal will continue to be used, but you will no longer be contacted and no further data will be collected.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. Your participation in this study is voluntary. Your refusal to participate will not prejudice your future treatment or benefits. You are free to discontinue participation in the study at any time without fear of penalty or loss of medical care or loss of any benefits to which you may otherwise be entitled. If you choose to withdraw from this study, or if the investigator withdraws you from the study, no further information will be collected from you or about you. You should know, however, that the information collected about you up to the time of your withdrawal may continue to be used.

Is there any way being in this study could be bad for me?

There are no foreseeable risks associated with the neurological testing. It is possible that you may become fatigued and/or feel uncomfortable answering questions in the neuropsychological, or vocational examinations. If so, you can stop, or decline to answer at any time.

The side effects that may occur with Acthar® (Adrenocorticotropic Hormone) are related primarily to its steroid-like effects similar to IV Solumedrol (Methylprednisolone). There may be increased susceptibility to new infection and increased risk of reactivation of latent infections.

Acthar® (Adrenocorticotropic Hormone) may cause various side effects such as:

- Dizziness
- Nausea
- Anaphylactic or hypersensitivity reactions
- Hypertension (high blood pressure)
- Congestive heart failure
- Thin, fragile skin
- Erythema (redness of the skin)
- Increased sweating
- Increased requirements for insulin or oral hypoglycemic (low blood sugar) agents in diabetics
- Elevated blood sugar
- Cushing's syndrome

- Gastrointestinal perforation and bleeding or peptic ulcer
- Pancreatitis (inflammation of the pancreas)
- Abdominal distension (enlargement)
- Water retention
- Peripheral edema (swelling of the extremities)
- Headache
- Impaired wound healing
- Ecchymosis (bruising)
- Menstrual irregularities
- Loss of muscle mass
- Thinning of the bones
- Cataracts
- Glaucoma
- Onset or worsening of euphoria, insomnia, irritability, mood swings, personality changes, depression, anxiety and psychosis
- Fatigue
- Injection site pain

Pregnancy

Acthar® (Adrenocorticotropic Hormone) may hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. You should not be or become pregnant while in this research study. If you become pregnant, continuing the study drug may not be safe for your unborn baby and for yourself. Therefore, you must report the pregnancy immediately to the site's staff and your participation in the study will be stopped.

Other Risks:

There may be other side effects, which are unknown at this time.

As with all other medications, you should be aware that you may develop some side effects to the study drug. You will be watched carefully for any side effects and you must report changes in your condition to your study physician.

Will being in this study help me in any way?

You may or may not have any direct benefit by participating in this research. This study is designed to learn more about Acthar® (Adrenocorticotropic Hormone). The study results may be used to help other patients in the future. Results of the Neuropsychological testing will be available upon request.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval upon your neurologist's request. Circumstances that could possibly lead to your withdrawal would be if continuation of treatment with Acthar is no longer in your best interest, based on your treating clinician's judgment. Your treating clinician may remove you from the study at any time should he/she feel it is no longer in your best interest.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research study is being funded by Mallinckrodt (formerly Questcor) Pharmaceuticals. Acthar (Adrenocorticotropic Hormone) will be provided to you through the study.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The Research Foundation of SUNY Buffalo has no program to pay for medical care for research-related injury.

If you agree to take part in this research study, we will pay you $200 for your time and effort.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

X Information from your full medical records:

X New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

Provide a general description of information that will be collected:
We will collect information on your disease course and MS symptoms, medications, physical and neurological testing data.

B. Who is authorized to provide or collect this information?

X Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

X Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

X The sponsor of this research study is Mallinckrodt (formerly Questcor) Pharmaceuticals.

X This research is being conducted in association with the Research Foundation of SUNY Buffalo.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

X This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__X__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Ralph Benedict, PhD
UBMD Neurology
Conventus Medical Center
1001 Main St,
Fourth Floor
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

IRB ApprovalPeriod