Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: *Use of NPH versus Basal Bolus Insulin for Steroid Induced Hyperglycemia*

Investigator:
Mark E. Molitch, M.D.

Division of Endocrinology, Metabolism and Molecular Medicine

Supported By: This research is supported by Northwestern University

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are currently receiving steroids as a part of your care here at the hospital. We would like to investigate the best way to control your blood sugar while on these steroids.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

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.

Why is this research being done?

The goal of the study is to see which method of giving insulin will provide the best control of your blood sugar while you are receiving steroids for other medical conditions. There is no standard way to control blood sugars while on steroids, and we would like to find out if any method provides better control.

How long will the research last and what will I need to do?

We expect that you will be followed in this research study for three days during your hospital stay. However, we will continue to collect and analyze data over a two year time period.

There is nothing that you need to do during this time. The nurses will continue to give you the insulin and measure your blood sugar during your hospital stay.

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More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

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

There is always a risk of both hyperglycemia (high blood sugar levels) and hypoglycemia (low blood sugar levels) when managing hyperglycemia patients with insulin. However, we monitor your blood sugars very closely while in the hospital and will adjust the insulin as needed on a daily basis to minimize any risk.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

You will benefit from having your glucose levels monitored closely with frequent insulin adjustments made as needed by our Endocrine Consult Service or our Glucose Management Service.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Mark Molitch at

Northwestern University Feinberg School of Medicine

Division of Endocrinology, Metabolism, and Molecular Medicine

645 N Michigan Ave

Suite 530
Chicago, IL, 60611
312-695-7970

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This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- 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 have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 50 people will be in this research study.

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

You will be randomized to one of two research arms. You either may receive a type of insulin known as NPH along with your dose of steroids in addition to the standard Lantus and Lispro insulins you usually get or you will receive insulin in the form of Lantus and Lispro in increased doses to help control your blood sugars. Your sugars will be tested 4 times a day, which is routine regardless of whether you are in the study or not. You will be followed by the Endocrine Consult Service or Glucose Management Service who will adjust your insulin doses according to your blood sugars. We will collect data from the chart for three days while you are in the hospital and receiving steroids. All of the research will take place while you are here at Northwestern Memorial Hospital. You will interact with the members of our team including nurse practitioners, the attending physician, and the endocrine fellows.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment.

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

If you take part in this research, you do not have any responsibilities. We will manage your sugars and check your blood sugars as we normally would while you are in the hospital

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.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data.

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

Both hyperglycemia and hypoglycemia are inherent risks with inpatient blood glucose management with insulin. Every effort will be made to reduce these by at least daily review of

blood glucose levels on every participant with adjustments of insulin doses as needed. These risks would be there regardless of being in the study as you would be on insulin already as a part of your routine care.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "What happens to the information collected for the research?".

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, as with all patients seen by our consult services, you will benefit from having your glucose levels monitored closely with frequent insulin adjustments made as needed.

Society and investigators will benefit from the knowledge gained.

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 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 institution.

An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

All glucose and demographic information will be stored on anonymized confidential files stored in firewalled Northwestern University computers. A separate file will be kept with a patient number and any identifiable information and stored in these firewalled computers.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal: If your primary treatment team changes your steroid regimen that does not fit within the inclusion criteria for our study, you can be removed from the research.

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What else do I need to know?

If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.
The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy

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[except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases: The following registries: Enterprise Data Warehouse

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the recievers of the information except in precise situations allowed by law.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Mark E. Molitch, M.D.

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Division of Endocrinology, Metabolism and Molecular Medicine
Department of Medicine
Northwestern University Feinberg School of Medicine
645 N. Michigan Ave, Suite 530
Chicago, IL 60611
(312) 503-4130

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

For Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Printed Name of Legally Authorized Representative Date

_____ _____

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Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent Date