Automated Insulin Delivery for Inpatients With Dysglycemia (AIDING) Randomized Controlled Trial

NCT06418880

October 4, 2025

You Are Being Asked to Be in a Research Study

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of up to 135 people who are being studied at Emory University/Grady Health System, Stanford University, and University of Virginia.

Why is this study being done?

The study is being done to find out if an automated insulin delivery (AID) system can be used in hospital to help manage glucose levels. You are being asked to be in this research study because the knowledge gained from this study may be used to help others. Research studies are not intended to benefit you directly.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for up to 10 days in the study (or until discharge if this occurs before 10 days). During this time, you will wear a continuous glucose monitoring (CGM) device with or without an insulin pump. You will receive 1 of 2 devices chosen by randomization, like the flipping of a coin. All devices will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers to understand more about the use of AID to manage high blood sugars in the hospital. The potential benefit of using AID in the hospital is the improvement in blood sugar levels.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The device that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like feeling bored during the study procedures. Some are more serious – the most likely risks to you are getting high or low blood glucose levels. You may also get redness, itching, or discomfort from the continuous glucose monitoring sensor or insulin pump adhesive tape. You may also feel pain or bruising from fingersticks, blood draws, or where the insulin pump or

glucose sensor are placed just under the skin. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

If you decide to not enter this study, there is care available to you outside of this research study. You should know that there are other types of diabetes drugs and insulins available to treat elevated blood sugar in the hospital. The study doctor will discuss these options with you. You do not have to be in this study to be treated for diabetes in the hospital.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. There is more information in the cost section further below.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.)
4. Make sure you understand which parts of these are research and which are standard care that you would have even if you did not join the study.
5. Take time to consider this and talk about it with your family and friends.

Consent to be a Research Subject / HIPAA Authorization

Title: Automated Insulin Delivery for INpatients with DysGlycemia (AIDING) Randomized Controlled Trial.

IRB #: STUDY00007081

Investigator-Sponsor: [redacted] MD, MPH

Study Sites/PI: Emory University and Grady Health System
[redacted], MD, MPH

Stanford University
[redacted]

University of Virginia
[redacted]

Study Supporters: National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases, Insulet Corporation, and Dexcom Inc.

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

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.

Who is doing this study?

This study is being done by Emory University/Grady Health System, Stanford University, and University of Virginia. It is being paid for by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Insulet Corporation and Dexcom will support the study with devices for the automated insulin delivery (AID) system. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's contact information is listed in this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study, they have to tell Emory University who is coordinating the study, and this information is provided to you in this informed consent.

What is the purpose of this study?

Use of an automated insulin delivery (AID) system in the hospital is being studied. The AID system being studied is called the Omnipod 5 AID System. The AID system is made up of three parts: (1) a continuous glucose monitor (CGM) that measures glucose levels; (2) an insulin pump ("pod") that delivers insulin; and (3) a computer program on a dedicated cell phone ("controller") that can tell the pump how much insulin to give you.

This is how the AID system works. The CGM measures your glucose level and sends this information to the insulin pump ("pod"). Each Pod contains technology that adjusts insulin every 5 minutes to bring your glucose value to your customized glucose target, or Target Glucose. The adjustment is based on a prediction of where your glucose will be 60 minutes in the future.

The pod holds insulin. It delivers insulin to your body through a small flexible tube called a cannula that is just under the skin. The pod is disposable. It must be replaced every two to three days or if it stops working. The controller is used to monitor your glucose values and to deliver mealtime insulin, insulin to correct high sugars, or to make changes to your insulin delivery settings. The controller will send your CGM values and insulin doses to a data portal. This allows the study doctors to remotely review your data for safety.

The CGM sensor used in this study is made by Dexcom, Inc. This sensor is called the Dexcom G7. It includes two parts: the sensor and a transmitter. The CGM sensor is also placed under the skin. The sensor measures the glucose in the fluid under the skin every five minutes. The transmitter snaps onto the sensor and relays the blood sugar values to the pod. The software on the pod uses the blood sugar values from the sensor to decide how much insulin to deliver. The Dexcom G7 sensor lasts 10 days. It may be replaced sooner if it comes out or stops working. The Dexcom G7 uses a web program called Clarity to allow for remote monitoring of glucose values. The study team will set up an account in Clarity to access CGM data remotely. This information will be stored in a secure database. No personal information will be shared through this platform.

The study AID system is approved by the US Food and Drug Administration (FDA) for patients with type 1 diabetes for use in the home setting. The study AID system is not approved for use in the hospital for patients with type 1 or type 2 diabetes. For this reason, it is called experimental. The study system will be managed by the study doctor and hospital nursing team. You will not interact with the study device, except to wear the pod and CGM sensor.

What will I be asked to do?

If you decide to participate in the study and sign this consent form, we will ask you questions about yourself, your diabetes, and your health. A physical exam will be done. There may be a blood draw to check your hemoglobin A1c if this has not been done. A urine pregnancy test will be done for females who have the potential to become pregnant.

Your diabetes treatment in the hospital will be decided randomly (by chance or like flipping a coin) and about half of the patients in the study will be assigned to each treatment. You will either use an insulin pump and CGM (AID system) or usual insulin therapy along with a CGM device.

If you have type 1 diabetes and are using an insulin pump that is not connected to CGM for AID, you may continue using the insulin pump per hospital usual practice if by chance you are selected to be on the usual insulin therapy group.

We will start use of the study devices if you are eligible for the study and want to continue. If you do not qualify for the study or decide not to continue, that is okay. Your doctor's team will discuss your options.

1. CGM (continuous glucose monitor): measures your blood sugar every 5 minutes. This device sends information to the insulin pump (2. Pod) for insulin dose administration
2. Insulin pump (Pod): This device delivers rapid-acting insulin continuously through a small catheter inserted under the skin.
3. Controller: the controller displays your blood sugar trends and allows to adjust your insulin as needed.

Study System Start-Up

The study doctor will set up the study AID system. They will place and insert the insulin pod and CGM sensor on your body. The team will also program the controller (study cell phone).

Study System Use

You will be asked to use the system for 10 days or until you are released from the hospital if this happens earlier. The study or hospital team will remotely deliver meal and correction insulin doses using the controller. The study pod and CGM may be removed for any imaging scans or other required testing procedures and replaced after these procedures are completed.

A fingerstick blood glucose test will be completed if your CGM sensor has a blood glucose value <80 mg/dL. Additional fingerstick blood glucose tests may be completed as needed to treat a low blood sugar. A fingerstick blood glucose check is needed to confirm the CGM sensor is giving an accurate glucose value. CGM sensors not providing an accurate value for 12-24 hours will be replaced. If the CGM is still not reading accurately after 48-hours, the AID system will be stopped. You will then be placed on standard insulin therapy per the hospital guidelines.

For participants on AID, an optional extension period for 10 additional days of AID use will be permitted. Extension periods are intended to allow participants to prolong system use in cases where transition back to usual care would be suspected to worsen glycemic control.

CGM Monitoring
The nursing team will be able to review your CGM data outside your hospital room. They will receive alarms if your blood sugar is too low.

The study doctor/research team will also be able to remotely review your CGM values. The research team will receive alerts if your blood sugar value is:

- >250 mg/dL
- <80 mg/dL
- No CGM glucose readings for 30 minutes

The research team will contact the hospital nursing staff if you need a correction insulin dose or to check your insulin pod or settings.

In the control group, blood sugar control will follow established medical guidelines with the assistance of an endocrinology management team. Standard procedures for insulin administration, as established by the nursing staff, will be adhered to.

Study System Stop
The study or hospital team will stop the AID system after 10 days of use or when you are released from the hospital if that happens sooner. The study pod and CGM sensor will be removed. You will start standard insulin therapy per hospital guidelines or resume your usual home therapy.

Patients with type 1 diabetes or patients with type 2 diabetes requiring insulin will be included in this study. If you are a woman of child-bearing potential, you will take a pregnancy test one time prior to enrollment in the trial.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not be given any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

Hypoglycemia (Low Blood Glucose)
As with any person who uses insulin, there is always a risk of having low blood glucose, or hypoglycemia. Symptoms of low blood glucose can include:

- sweating
- shaking
- not feeling well
- fainting
- seizures

In very rare cases low blood glucose can lead to coma, brain damage, or death. Even if low blood glucose does occur, it almost always goes away quickly with treatment to raise the blood glucose.

Hyperglycemia (High Blood Glucose)
Hyperglycemia usually does not cause many obvious symptoms. You may be thirsty or have a higher level of glucose in your urine. In severe cases of hyperglycemia, diabetic ketoacidosis (DKA) or coma may occur. When there is not enough insulin present, the body cannot use sugar (glucose) as fuel and fat is used for fuel instead. When fat breaks down, it

produces ketones which can build up in the body. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown, and even death. DKA can occur quickly in someone using a pump if the infusion set gets disconnected or some other problem occurs so that insulin is not being delivered.

Fingerstick Risks
It may hurt when the lancet goes into your finger but not for long. In about one in ten cases, a small amount of bleeding under the skin will cause bruising. The risk of an infection is less than one in 1,000.

Insulin Pump/Pod Risks
The risks of using an insulin pump may include:

- Slight discomfort during insertion of the infusion set (common)
- Slight bruising at the site of infusion set insertion (common)
- Infusion set occlusions (common)
- Hyperglycemia secondary to occlusion or infusion site failure (common)
- Pump malfunction and mechanical problems (common)
- Lipodystrophy/lipoatrophy (hard lumps in fatty issue) (common)
- Bleeding at insertion site (rare)
- Infection at insertion site (rare)
- Allergy to the infusion set or adhesive (rare)
- Allergy to insulin (very rare)

Continuous Glucose Monitoring (CGM) Risks
Potential risks from using a CGM include:

- Discomfort when the sensor is inserted into the skin (common)
- Bleeding at the insertion site (common)
- Allergy to CGM sensor adhesive material (common)
- Slight bruising at the insertion site (unlikely)
- Infection at the insertion site (rare)
- Sensor breakage or damage (rare)

AID System Risks
There is still a risk that parts of the system may not work right even though the system has been tested extensively prior to this study. As a result, more or less insulin than what you need could be delivered. This could lead to hypoglycemia or hyperglycemia. The following are possible reasons the system may deliver too much insulin or incorrectly stop insulin delivery:

- CGM sensor reads higher or lower than your actual glucose level
- Part of the insulin infusion system doesn't work correctly
  Risk if sensor glucose is inaccurate when auto correction (auto bolus) is active:
- There is a risk of hypoglycemia if a sensor glucose is much higher than a blood glucose at that time. The amount of insulin delivered could be larger than if blood glucose was used.
- If you feel low, you should inform the nurse.

Risk if sensor glucose is inaccurate in calculating a meal bolus:

- There is a risk of hyperglycemia if a sensor value is much lower than a blood glucose at that time. The amount of insulin delivered could be smaller than if blood glucose was used
- There is a risk of hypoglycemia if a sensor glucose is much higher than a blood glucose at that time. The amount of insulin delivered could be larger than if blood glucose was used.
- If you feel low, you should inform the nurse.

Standard therapy
The risk of standard therapy may include:
Slight discomfort at injection site
Bruising injection site
Hypoglycemia
As with any person who uses insulin, there is always a risk of having low blood glucose, or hypoglycemia. Symptoms of low blood glucose can include:

- sweating
- shaking
- not feeling well
- fainting
- seizures

In very rare cases low blood glucose can lead to coma, brain damage, or death. Even if low blood glucose does occur, it almost always goes away quickly with treatment to raise the blood glucose.

Risks for Unborn Babies
High or low blood sugars can be harmful to an unborn baby or to an infant who is breastfeeding. The risks of the AID system used in this study on an unborn baby are unknown. Anyone who is pregnant, or breastfeeding cannot be in this study. Urine pregnancy tests are done as part of this study for anyone that is considered to be able to get pregnant. For example, anyone who has started having menstrual periods, or is still having menstrual periods, will have pregnancy tests no matter how young or old they are. The study doctors are required to do this even if someone thinks there is no possibility of pregnancy.

Unknown risks
It is always possible that anyone using a device for the first time may have an allergic reaction. Also, there may be additional risks from the device or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Risks to Confidentiality
This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

Will I benefit directly from the study?
This study is not designed to benefit you directly. If you are in the study, you will be helping the researchers to understand more about the use of AID to manage high blood sugars in the hospital. The potential benefit of using AID in the hospital is the improvement in blood sugar levels. The study results may be used to help other patients with high sugars in the hospital. However, glucose control and the risk of adverse events may worsen.
Will I be paid for my time and effort?
You will receive $100 for participating in the study which may last up to 10 days or until you are ready for discharge, which can occur before 10 days. You will receive half of the compensation ($50) if you decide to stop your participation before the study is completed.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You should know that there are other types of diabetes drugs and insulins available at your enrolling site to treat elevated blood sugar in the hospital. The study doctor will discuss these with you. You do not have to be in this study to be treated for diabetes while you are hospitalized.

Taking part in this study, however, may make you unable to participate in some other research studies in the hospital. You should discuss this with the researchers if you have concerns.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality
There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and your enrolling site will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory or your enrolling site received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory or your enrolling site from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing Your Information
De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

If you join this study, you will be donating your study information. You will not receive any compensation if your data are used to make a new product. If you withdraw from the study, data that were already collected may still be used. These data may be kept indefinitely and used for future studies involving to test for other abnormalities such as how your body controls glucose. We may also use the data in this study for future studies without another consent. If you want us to destroy your data, you will need to send this request in a letter to:

[redacted]

What if I get ill or injured?
If you get ill or injured from this research, contact the person listed in the contact section of this form. Your enrolling site study team will help you get immediate medical care. However, Emory, your enrolling site, and the Federal Government (including but not limited to the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Will it cost me anything?
The study sponsor will pay for certain items and services that you may receive if you take part in this study. The AID system will be provided by Insulet at no cost.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, your enrolling site will submit claims to your insurance for items and services that the sponsor does not cover. Your enrolling site will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and your enrolling site and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information
If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact:

- Dr. [redacted]
- Dr. [redacted]
- Dr. [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

Optional Consent for Future Contact

The researcher may wish to contact you in the future about additional research studies. Please check the appropriate statements to indicate whether you give permission to share your information for future contact.

☐ I give permission to share my information to be contacted in the future about additional research studies.
☐ I do not give permission to share my information to be contacted in the future about additional research studies.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date** **Time**