DEMONSTRATION OF AN ARTIFICIAL INTELLIGENCE BASED CLOSED LOOP GLUCOSE CONTROL SYSTEM AS A THERAPEUTIC MODALITY IN TYPE 2 DIABETIC PATIENTS

NCT Number: 05386849

Principal Investigator: Dr. Francisco Pasquel

April 20, 2022

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

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 2 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question if the new device FUSION is useful to adjust insulin treatment in the hospital or intensive care unit (ICU) setting. You are being asked to be in this research study because you are between 18 to 70 years and have type 2 diabetes diagnosis.

Do you have to be in the study?

It is your choice to join 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 choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will have 3 study visits. During visit 3 you will spend about 28-32 hours in the clinical research center at Emory University Hospital. A medical device will control your blood glucose level with IV infusions of insulin and/or glucose (sugar) for 24 hours. All of these procedures 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 answer the study question.

What are the risks or discomforts you should know about before deciding?

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 being bored or losing time. Some are more serious. Risks for this study include:

- Low blood sugar, high blood sugar.
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is a research study, the alternative is not to take part. If you choose to not take part in this study, you will continue to receive your usual diabetes care in the Diabetes Center at Grady Health System or adult Endocrinology Clinic of Emory Healthcare.

Costs
There will be no costs to you for taking part in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the “Costs” section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject/ HIPAA Authorization

Title: **DEMONSTRATION OF AN ARTIFICIAL INTELLIGENCE BASED CLOSED LOOP GLUCOSE CONTROL SYSTEM AS A THERAPEUTIC MODALITY IN TYPE 2 DIABETIC PATIENTS**

IRB #: STUDY00002027

Principal Investigator: Francisco Pasquel, MD, MPH

Sponsor: Ideal Medical Technologies

Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to determine the use of a new device to adjust insulin treatment in the hospital or intensive care unit (ICU) setting, including those patients who have been admitted with COVID-19. Research studies are voluntary. You do not have to be in this study if you do not want to. We ask that you read this form and ask questions. If you agree to be in this study, you will need to sign and date the consent form before any study procedures are done. Two subjects 18 to 70 years who have type 2 diabetes will take part in this study.

Before any testing is conducted, we will ask you to sign this form. We will ask you questions about your medical history to ensure that you meet the study inclusion and exclusion requirements. We may ask you to provide a blood specimen. We do not know if use of the study device during pregnancy poses a risk. As a precaution, if you are female and of child-bearing age, you will have to take a pregnancy testing before joining the study. You will not be in the study if you are pregnant.

Background Information

High blood sugar levels in patients admitted to an intensive care unit (ICU) and hospitalized due to COVID-19 have been associated with increased mortality rates. However, attempts to lower sugar levels, known as tight glucose control, is difficult to achieve in the hospital or ICU setting. Insulin administration is needed to control sugars levels in hospitalized patients. During insulin treatment, many patients develop low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia) levels. In this study we will test a glucose control system that is based on artificial intelligence (AI), to see if it can keep blood sugar levels in the normal range. This device is not FDA approved and this will be the first time it is used in humans. The study will take place in a highly controlled environment so we can closely monitor your blood sugar levels.

What will you be asked to do?

Procedures:

The study will take place in a clinical research center at Emory University Hospital. You will spend about 32 hours in the research center during the study. You will be treated with a medical device that uses intravenous (IV) infusions of insulin and/or glucose to control your blood glucose level. Your blood glucose levels will be controlled with this medical device for a period of 24 hours.

Clinical Study Protocol:

During the screening visit (visit 1) we will obtain your medical history and confirm that you meet the requirements for the study. During visit 2 we will obtain your consent to participate in the study and you will receive information to prepare for visit 3 (see below).

Visit 3 (admission to the research unit at Emory University Hospital)
After admission, two IV lines will be placed in your arms; one for insulin and/or glucose infusion and one to monitor blood glucose.
Two Dexcom G6 continuous glucose monitors (as shown in the picture below) will be placed in your skin near your belly button. Every five minutes, the monitors will send your sugar values to the medical device being used to control your blood sugar levels via a Bluetooth signal.

The FUSION medical device will use the blood sugar values obtained from the Dexcom G6 monitors to adjust the amount of insulin or glucose that you get to keep your blood sugar in the normal range. The medical device may adjust your insulin and/or glucose every 5 or 10 minutes for 24 hours.

During the study time:

- You will be in the clinical research center for at least 31 hours – 7 AM on day 1 to 2 PM on day 2.
- During your first 5 hours, (7 AM to 12 PM on day 1) you will be prepared for the study
    - This preparation will include:
        - Measurement of your weight, height, and vital signs.
        - Placement of the two Dexcom G6 CGMs
        - Placement of 2 IV lines.
- Once the Dexcom G6 CGMs begin to send sugar values to the Dexcom Receivers, the 24-hour control session will begin.

During the 24-hour control session the following will occur:

- Your blood sugar levels will be controlled by the medical device.
    - Your blood sugar levels will be measured every 10-60 minutes from one of the IV lines in your hand. You will have between 50 mL and 80 mL of blood drawn.
- We will warm your hand with the IV line to about 120 to 140 degrees Fahrenheit with a warming pad.
- We will measure your heart rate, blood pressure, and temperature.
- We will give you lunch with 60 grams of carbohydrates at the beginning of the control session (approximately 12 PM on day 1), dinner with 75 grams of carbohydrates at 6 PM on day 1, and breakfast with 50 grams of carbohydrates at 8 AM on day 2.
- You may drink water but no drinks with sugar during your session. You may have snacks, on request, from 9 PM on day 1 until 6 AM on day 2.
- You will be confined to bed or a bedside chair.
- You will be given a bedside commode for your bathroom needs.

After the 24-hour closed loop glucose control session:

- You will eat a meal with 60 grams of carbohydrate and give yourself a dose of short acting insulin like you would at home.
- We will remove the two Dexcom G6 continuous glucose monitors and IVs.
- You will be able to go home once you have 4 normal blood sugar levels in a row.

We will mail you the results of how well your blood sugar was controlled by the device. We will call you after you go home to make sure you have not had any issues where the two Dexcom G6 continuous glucose monitors were inserted.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?

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

- **Severe hypoglycemia** in which your blood glucose level could drop below 54 mg/dl. Another potential risk with this study is **moderate hypoglycemia** (glucose 54-69 mg/dL) with the presence of severe cognitive impairment, such as altered mental status, confusion, or a possible seizure**. To avoid risk in this study**, we will *monitor your glucose levels every 10-60 minutes*. We will stop the study if your glucose levels drop below 54 mg/dl on more than one occasion. If you experience severe hypoglycemia (< 54 mg/dL) or moderate hypoglycemia (54-69 mg/dL) with symptoms, we will give you a rescue dose of 15 mL of 50% dextrose to raise your blood glucose to a safe level.
- **Bruising and hematoma** (hematoma is a localized bleeding outside of blood vessels) at the site of your IV line or blood collection site.
- **Infiltration (extravasation)** of IV fluid at your IV infusion site, which may cause swelling and pain at the site.
- **High blood glucose after the study:** We will resume your home medications after the study. We may adjust your doses so you can transition back to your previous regimen.

In addition to the risks detailed above, the additional risks associated with participation in this study are **minimal** and are mostly limited to inserting a continuous glucose monitor sensor and wearing the adhesive patch that holds the glucose sensor in place. Risks include:

- Local infection (extremely rare cases)
- Inflammation
- Lightheadedness
- Pain or discomfort
- Bleeding at the continuous glucose monitor sensor insertion site
- Bruising, itching, scarring or skin discoloration
- Hematoma (also known as a black and blue mark) caused by the leakage of blood under the skin, tape irritation, continuous glucose monitor sensor or needle breakage during insertion, wear, or removal.

All reasonable and necessary measures will be taken to protect you from infection and to prevent any unforeseen discomfort or events. You should seek professional medical help if you have symptoms of infection or inflammation (redness, swelling or pain) at the insertion site after your discharge from the clinical research center.

Will you benefit from the study?

You will not benefit from joining the study. However, you are being given the opportunity to take part in a scientific research study that may ultimately benefit hospitalized patients with diabetes, hospitalized COVID-19 patients, and ICU patients if the medical device under study is shown to provide safe and effective glucose control and is approved for use by the FDA. The study results may be used to help others in the future.

Will you be paid for your time and effort?

Within one month after you complete the 24-hour control session, we will mail you a gift card for $300 for taking part in this study. This payment will be mailed to you within one month of the day you complete the study in the clinical research center. You may be asked to fill out a tax form with your Social Security or Taxpayer Identification Number depending on the amount and method of payment. If your payment will be sent to your house in the mail and could be seen by others in your household, you can choose not to be compensated. You can decline payment if you are concerned about confidentiality, or you can talk to the study team if there are other ways to be compensated.

What are your other options?

If you choose not to join this study, you will continue to receive your usual diabetes care in the adult Diabetes Center at Grady Memorial Hospital or Endocrinology Clinic of Emory Healthcare.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

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.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you. Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Returning Results to Participants/Incidental Findings

You will be told about any new information that might change your decision to be in this study.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory medical record. If you have never been an Emory or Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Grady Hospital/Emory Healthcare System places may not become part of your Emory Healthcare System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this study, you should contact Dr. Francisco Pasquel at telephone number 404-778-1695-. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. "Negligence" is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study device or a study procedure, the sponsor Ideal Medical Technologies will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory employee.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study.

You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. The sponsor will pay for the cost of the devices, the IV insulin and glucose used for glucose control, and the staff to run the study. You will not be charged for any required labs or the medical device. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

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

You are volunteering yourself to take part in this study. You may withdraw from this study at any time, without prejudice. If you decide not to take part, or withdraw, you will not be penalized and will not give up any benefits that you had before entering.

You may leave the study at any time. You may notify the study coordinator at any time if you do not want to continue in the study. You can do so by calling the Study Doctor, Dr. Francisco Pasquel, at the phone number 404-778-1695.

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

The Sponsor, Study Clinicians, FDA, or IRB may end your participation at any time without your consent if thought appropriate. If you withdraw or are withdrawn from the study early you may be asked to perform study exit procedures.

Stopping the Study:

The Study Site or Study Sponsor may end your participation in the study at any time without your consent. Your participation may be discontinued if the Study Site or Study Sponsor decides that it is in your best interest, if you fail to follow the study requirements, if the Sponsor stops the study, or if the Sponsor deems it appropriate.

New Findings:
You will be told about any new information that might change your decision to be in this study.

Legal Rights
You do not lose any legal rights by signing this consent document. The above statement, "Compensation for Injury," does not stop you from getting legal help in case of negligence.

Who is paying for this study?
This research is being paid for by Ideal Medical Technologies, who is the maker of the study device.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not take part in the research study.

Research-Related Treatment
This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory and Grady Health Systems may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- **Ideal Medical Technologies** is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory and Grady Health Systems offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Grady Research Oversight Committee, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including Food and Drug Administration
    - Public health agencies.

  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact Dr. Francisco Pasquel at: 69 Jesse Hill Jr. Dr SE, Atlanta, GA 30303.

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

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. Francisco Pasquel at 404-778-1695**
You may ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study participant;

- Eligibility to take part in the research;
- The Study Clinicians' or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

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.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent, confidentiality agreement and HIPAA Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. 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**