COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE-NEW HAVEN HOSPITAL

Study Title: CAPO: Continuous glucose monitoring in A2 Gestational Diabetes and Pregnancy Outcomes

Principal Investigator (the person who is responsible for this research):
Audrey Merriam, MD, MS
PO Box 208063
New Haven, CT 06520-8063
Phone Number 203-785-7813
24-Hour Phone Number: **315-420-4590**

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to determine if use of a continuous glucose monitor worn on the arm or abdomen improves outcomes for women with gestational diabetes on medication and their infants
- Study procedures will include: randomization to use of a continuous glucose monitor versus usual monitoring for gestational diabetes (checking fingersticks with a glucometer 4 times a day)
- No more than the usual number of prenatal care visits are required, which will vary depending on when in pregnancy gestational diabetes is diagnosed but is expected to be no more than 10 visits.
- These visits will take 1 hour for the initial visit and consent process and then anywhere from 15-60 minutes for follow up visits depending on what is required at the usual prenatal visit.
- There are some risks from participating in this study. Risks to participation are minimal. If randomized to the usual care group, you may have pain and bleeding from the sites of the fingersticks. If you are randomized to the continuous glucose monitor group, you may have irritation or mild discomfort at the time the monitor sensor is inserted. In rare cases, the sensor has broken off in the skin and will need to be removed. There could be pain, redness or swelling at the site of monitor insertion.
- The study may have no benefits to you. If you are randomized to the continuous glucose monitoring group, you could avoid fingersticks four times a day to monitor your blood sugar. This may also change how we monitor women with gestational diabetes in the future.
- There are other choices available to you outside of this research. You could choose not to participate in this study. Monitoring your gestational diabetes will then occur with fingersticks four times a day and checking your blood sugar with a glucometer.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you have been diagnosed with gestational diabetes in your third trimester requiring medication to manage your blood sugars. We are looking for approximately 134 participants to be part of this research study.

Who is paying for the study?

Dexcom has provided the devices for use in this study and no additional funding is being utilized.

Who is providing other support for the study?

None

What is the study about?

The purpose of this study is to determine if use of a continuous glucose monitor worn on the arm or abdomen improves outcomes for women with gestational diabetes on medication and their infants. A continuous glucose monitor is a device placed on the upper arm or abdomen that allows your blood glucose level to be monitored continuously without the use of fingersticks and a blood glucometer. The device does require changing every 10 days and uses a small needle to monitor your blood glucose in the sensor. The sensor then uses an application on your phone to monitor your blood glucose and you must have a smartphone in order to have access to the Dexcom application to participate in the study. These results are then reviewed at your prenatal visits.

The study will used with Dexcom G6 continuous glucose monitor (CGM) from Dexcom. The device is approved for use by the Food and Drug Administration (FDA) outside of pregnancy but has not yet been evaluated thoroughly for use in pregnancy, and is currently not approved for used in pregnant women. This device has been evaluated in other studies in pregnant women and has shown improvement in pregnancy outcomes. Dexcom recently completed a trial in pregnancy utilizing the G6 CGM device but the results are not yet available.

Discover the Dexcom G6 CGM System

1. Simple auto-applicator 0 a one-touch applicator easily inserts a small sensor just beneath the skin. (1)
2. Sensor and transmitter – a slim sensor continuously measures glucose levels just beneath the skin and sends data wirelessly to a display device through a transmitter (2)
3. Display device – a small touch screen receiver or compatible smart device (i.e. smartphone) displays real-time glucose data (3)

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

- Shortly after signing the consent you will be randomized, like flipping a coin,to receive a continuous glucose monitor (study group) or continue monitoring your blood sugars as you have been with fingersticks and a glucometer (control group).

- If you are randomized to the continuous glucose monitor group you will have an educational session on how to use the device with our diabetes nurse educator. This may take an additional 15-30 minutes the day you receive the device.
- If you are randomized to the control group at 32-33 weeks you will have an educational session with the diabetes nurse educator on the continuous glucose monitor device. You will be asked to wear this device for the next 10 days while you continue to check your blood sugar 4 times a day as previously instructed. The information from the continuous glucose monitor will not be used to guide your gestational diabetes management during this time but will later be used (after you have delivered) to look at your blood sugars during this time to examine what your blood sugar does overnight
- Your prenatal care will continue as normal and we will gather information on your weight gain, your blood sugar values, need for medication adjustments, estimated fetal weight by ultrasound and other routine data gathered as part of your gestational diabetes care
- No additional visits will be required outside of your scheduled prenatal visits or visits to the Yale Diabetes in Pregnancy clinic at the Yale Maternal-Fetal Medicine office. However, if you are having difficulty with taking your fingersticks or use of the CGM you will be scheduled for an urgent visit with our diabetes nurse educator. Additionally, if the values on the CGM or with fingersticks show a lot of variation/fluctuation you will be brought in for an urgent visit with the diabetes nurse educator. - At your visits we will review your blood glucose control and make medication adjustments as needed if you are in the continuous glucose monitor group or in the group using fingersticks and a glucometer to monitor your gestational diabetes
- We will also be looking at several things about you including your age, prior pregnancy and delivery history, BMI, medications during pregnancy, gestational age, antenatal admissions, ultrasound findings, maternal weight at delivery, maternal blood glucose values and neonatal weight at birth, neonatal blood glucose at birth and throughout the hospital stay, APGAR scores and admission to the NICU.
- After you deliver you will be asked to complete a short survey about your experience with the continuous glucose monitor device and managing your gestational diabetes during pregnancy

What are the risks and discomforts of participating?

Risks to participating in the research include any risk associated with wearing the continuous glucose monitor. The sensor wires for the CGM go under the skin and the device is placed by the patient after instruction from one of our diabetes nurse educators. Risks to wearing the device include minor discomfort at the time of device placement, skin irritation, redness, and swelling. Rarely the sensor for the device can break in the skin and require removal. The device has been deemed safe for use by the FDA in non-pregnant populations. Studies using CGM, particularly the Dexcom G6 CGM during pregnancy exist but it is not currently approved for use in pregnancy and there may be unknown risks associated with its use in this population.

If wearer is experience symptoms that may be related to hypoglycemia or hyperglycemia the reading on the sensor should be checked and then checked with a fingerstick and a blood glucose meter.

The sensor needs to be changed every 10 days in compliance with the device manual from Dexcom.

Before having a CT or MRI the device should be removed and a medical alert card will be given to participants with the CGM to inform medical personal that the device is in place and needs to be removed.

The standard of care is fingersticks and the CGM device is deemed to be as safe as fingersticks, which you have been doing prior to enrollment to monitor your gestational diabetes. Risks of fingersticks include pain and infection at the site of the needle stick.

There is the potential for loss of confidentiality with study data and steps will be taken to protect against this.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

By participating in this study, you may be randomized to the group with the continuous glucose monitor and eliminate the need for fingersticks four times a day to monitor your blood sugar. The continuous glucose monitor may allow you to have better control and knowledge of your blood sugar values which can improve outcomes for you and your baby. There is no guaranteed benefit to your or your baby from participation in the study since there is limited use with CGM in pregnancy.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of if using the continuous glucose monitor is an acceptable alternative to four times a day fingersticks for monitoring women with gestational diabetes. It may also allow us to understand if there are improved outcomes for mom and baby when this device is used.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits, which will be at the same time as your routine prenatal visits. If you are in the continuous glucose monitor group, the device and replacement sensors will be provided to you from the time of enrollment until you deliver. If you are in the control group, using fingersticks and a glucometer, you will have already had these materials covered by your insurance company.

Will I be paid for participation?

No financial compensation will be provided for this study.

What are my choices if I decide not to take part in this study?
Instead of participating in this study, you have some other choices.

You could continue routine monitoring of your gestational diabetes as you are already doing by using fingersticks and a blood glucomenter to monitor your blood glucose level four times a day. Your decision to participate or not will not affect your care in anyway.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.
Any data collected for the study will be stored in a confidential manner. Data will be de-identified and stored on a password protected drive.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held Yale New Haven Hospital created from the time of your gestational diabetes diagnosis to the time you and your infant are discharged from the hospital after delivery
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - HIV / AIDS test results
    - Hepatitis infection
    - Sexually transmitted diseases
    - Other reportable infectious diseases
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Records about the continuous glucose monitor

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The study sponsor - Dexcom
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study
- The U.S. Food and Drug Administration (FDA). This is done so the FDA can review information about the CGM involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing Dr. Audrey Merriam PO Box 208063 New Haven, CT 06520-8063.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while participating in this study, you will receive treatment as appropriate given your clinical condition by the medical team providing your care. You will not receive any other kind of payment. There are no plans to pay you for such things as lost wages, disability, or discomfort as part of this study. You do not give up any of your legal rights by signing this consent form.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. Your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You will still be responsible for any co-pays required by your insurance company for standard treatment. You do not give up any of your legal rights by signing this form

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary if you do not follow your routine prenatal visit schedule.

What will happen with my data if I stop participating?

If you wish, you may withdraw your data from this study at any time.
When you withdraw from the study, no new health information identifying you will be gathered from your electronic medical record after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight. The information collected will only remain in your electronic medical record as the post-partum pain scores and medications given are to remain, as they are part of your health records during your post-partum period.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203-785-7813.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.