INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Clinical Trial Using an Insulin Dosing Calculator on Hospital Admission

What is this study about?

The purpose of this study is to look at whether using a standardized calculator to compute insulin dosages results in acceptable rates of low blood sugar (hypoglycemia). Currently, hospitals rely on physician experience to calculate insulin dosage, and physician practices are variable.

What will happen if you participate in this study?

If you decide to be in this study, your hospital doctor will order insulin for you based on this calculator instead of calculating based on their experience. Your doctor will continue to monitor your blood sugar as usual and adjust your insulin as needed. The rest of your care will follow standard procedures.

Why might you want, or not want to, participate?

You may want to participate in the study to help contribute to better blood sugar management in the hospital. Using the insulin calculator has the potential to better control your blood sugar.

You may not want to participate in the study because this is our first trial with patients. There is a risk of your blood sugar going too low.

Low blood sugar (hypoglycemia) is a well-known risk when managing diabetes. Hypoglycemia side effects include tremors, sweating, racing heart, and anxiety. In severe cases, you may experience weakness, dizziness, confusion, seizure, coma, or even death. Your blood sugar levels will be closely monitored and managed as needed.

If you choose not to participate in the research, the care available to you will include standard of care methods of calculating insulin dosages. The research team will discuss these options with you and provide information about the risks and benefits.

How will we store, share, and protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members

of the study team and any individuals from the UW, National Institutions of Health (NIH), or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name.

This study is funded by the National Institutions of Health (NIH). We have a Certificate of Confidentiality from the U.S. federal NIH which allows us to protect identifiable research information stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish. There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

Research information that is placed in your medical record may not be protected by this Certificate. Ask a member of the study team for information about what research information will be placed in your medical record.

The Certificate expires when the NIH funding for this study ends. Currently this is June 30, 2028. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, the information may then be used for future research studies or given to another investigator without getting additional permission from you.

Other information about this study.

Participating in this study is voluntary. This means that you have the right to refuse to participate. It also means that if you do enroll in this study, you can decide to stop being in the study at any time without penalty or loss of care.

If you have been injured or otherwise harmed by participating in this study, you will be treated or referred for treatment. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. Our study team may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, you can contact the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

A description of this clinical trial will be available on https://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.

If the consent form is signed in our electronic consent system (REDCap), a copy of the consent can be generated that you can review, download, and/or print. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact Dr. Hou-Hsien Tony Chiang (htchiang@uw.edu).

What can you do if you want more information?

Talk to the study team. The doctor who admits you to the hospital is part of our study team. If you have further questions after taking to your hospital doctor, the primary investigator, Dr. Hou-Hsien Tony Chiang, can talk to you in the hospital during work hours (htchiang@uw.edu). We are here to help you understand the study. Please ask us any questions you may have, even about things that are not in this document.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division (hsdinfo@uw.edu or 206-543-0098).

Consent presenter statement

By printing my name on this form, I am attesting that I have provided the subject and/or their legally authorized representative (LAR) with information about this study. The participant/LAR has been given sufficient time to consider participation and I have answered any questions they had. The participant/LAR indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent	Date

Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Printed name of legally authorized representative (LAR)	Signature of LAR

Relationship of LAR to subject	Date

You will keep a copy of this form. Please keep it with your personal records.