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Document name:

Continuous Glucose Monitoring in the Intensive Care Unit (ICU) Participant Information Sheet

Title of the study:

Continuous subcutaneous glucose monitoring. A descriptive study of its use in critical patients

NCT number:

Not yet available

Date:

November 22, 2023

Participant Information Sheet

STUDY TITLE	Continuous subcutaneous glucose monitoring. A descriptive study of its use in critical patients
STUDY CODE	MCGUCI1
SPONSOR	*Samuel González López*
PRINCIPAL INVESTIGATOR	*Samuel González López*
CENTER	*HLA Moncloa Hospital*

Introduction

We reach out to you to provide information about a research study in which you are invited to participate. The study is titled "Continuous Subcutaneous Glucose Monitoring: A Descriptive Study of Its Use in Critical Patients" and has been approved by the Ethics Committee for Drug Research of the University Hospital of Getafe, in accordance with current legislation, Royal Decree 1090/2015 of December 4, Organic Law 3/2018 of December 5, on the Protection of Personal Data and guarantee of digital rights, and European Regulation 536/2014 of April 16, which regulates clinical trials with drugs.

Our intention is to ensure that you receive accurate and sufficient information to decide whether or not to participate in this study. Please read this information sheet carefully, and we will clarify any questions that may arise. If you have any doubts, you can contact Dr. Samuel González López or any medical professional in the Intensive Care Unit (ICU) at HLA Moncloa Hospital. Additionally, feel free to consult with anyone you deem appropriate.

Voluntary Participation

If you are reading this information sheet, it is because you or a represented family member is admitted to the Intensive Care Unit (ICU) at HLA Moncloa Hospital and has a subcutaneous continuous glucose monitoring (CGM) sensor in place. As you may be aware, this sensor is shaped like a white button the size of a one-euro coin and is placed on the skin surface, usually on the upper arm. The device is capable of measuring glucose levels every minute and informing the ICU medical and nursing staff.

First and foremost, it is important to clarify that, in this study, the care and treatments you receive will be the same whether you decide to participate or decline participation.

You should be aware that your participation in this study is voluntary, and you have the option to choose NOT to participate. If you decide to participate, you can change your

decision and withdraw your consent at any time, without affecting your relationship with your doctor or causing any harm to your healthcare.

We only request permission to review and collect information necessary to fulfill the study's objectives. The information will be collected from the data recorded in your medical history in a process known as pseudonymization (we will explain this process later).

Study Objective:

At times, glucose control treatment can lead to decreases known as hypoglycemia, some of which may have serious consequences. To mitigate potential severity, sensors like the one you have are equipped with alarms that alert us to possible hypoglycemia. These alarms enable healthcare professionals to take appropriate action to prevent these episodes from becoming severe or, at the very least, minimize their severity. The goal of this study is to identify occurrences of hypoglycemia, describe the type of ICU patients equipped with a CGM sensor in our unit, and outline the actions taken by healthcare professionals.

Study Activities:

The study will span a total of 4 years (2023-2027). No additional examinations or extra activities will be conducted on individuals participating in the study.

Risks and Discomforts of Participation:

Your participation in this study poses no additional risks or discomforts to you, as the device placement has already been performed according to the criteria of your responsible doctor.

Potential Benefits:

There is no direct benefit to participating in this study. However, your decision to participate contributes to advancing scientific knowledge about hypoglycemia, which may improve the treatment of patients at risk of experiencing this issue in the future.

Pregnancy Warning:

There are no contraindications.

Protection of Personal Data:

In the Intensive Care Medicine Service of HLA Moncloa Hospital in Madrid, we are committed to safeguarding your personal information. Both healthcare professionals and all researchers with access to patient data pledge strict confidentiality in accessing, collecting, and processing data stored in databases. They also commit to strict compliance with current legislation, including Law 41/2002 of November 14, regulating patient autonomy and rights and obligations regarding clinical information and documentation, Organic Law 3/2018 on the protection of personal data and guarantee of digital rights, and Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of individuals concerning the processing of personal data and the free movement of such data, repealing Directive 95/46/EC (General Data Protection Regulation).

To prevent third-party access to all data, a pseudonymized approach will be employed. Two databases will be constructed—one containing personal data (medical history number, name, and surname) associated with a code, guarded by the principal investigator and the collaborating medical team. Only they will have access to this database. The other database will contain no personal data and will be constructed with association codes and clinical data, accessible to other collaborators for data analysis. Under no circumstances will we sell the information to third parties for commercial benefit.

Contact for Questions:

If you have any doubts or need more information during your participation, please contact Samuel González López, the principal investigator of the study and associate doctor of the Intensive Care Medicine Service at HLA Moncloa Hospital. You can request his contact information at the Intensive Care Unit of HLA Moncloa Hospital (Av. Valladolid 83, 28008 Madrid).

Participant Consent Form/INFORMED CONSENT

STUDY TITLE	Continuous subcutaneous glucose monitoring. A descriptive study of its use in critical patients
STUDY CODE	*MCGUCI1 V4 22-11-2023*

I, _____:

☐ Have read the information sheet provided to me about the study.

☐ Have had the opportunity to ask questions about the study.

☐ Have received sufficient information about the study.

☐ Have spoken with <<investigator's name>>.

☐ Understand that my participation is voluntary.

☐ Understand that I can withdraw from the study:

At any time.

Without having to provide explanations.

Without affecting my medical care.

I will receive a signed and dated copy of this informed consent document.

I freely give my consent to participate in the study.

Participant's Signature

Date: //____

Investigator's Signature

Date: //____

When obtaining IC from individuals with modified capacity to give their IC:

Legal representative, family member, or de facto related person's signature

Date: //____

Investigator's Signature

Date: //____

(Name, signature, and date in the participant's own handwriting)

Participant Consent Form with Witnesses/INFORMED CONSENT

STUDY TITLE	Continuous subcutaneous glucose monitoring. A descriptive study of its use in critical patients
STUDY CODE	*MCGUCI1 V4 22-11-2023*

I, _____, as a witness, affirm that in my presence, D/Dª _____ has been informed and has read the information sheet provided about the study. Thus:

☐ Has had the opportunity to ask questions about the study.

☐ Has received sufficient information about the study.

☐ Has spoken with <<investigator's name>>.

☐ Understands that their participation is voluntary.

☐ Understands that they can withdraw from the study:

- At any time.
- Without having to provide explanations.
- Without affecting their medical care. I will receive a signed and dated copy of this informed consent document.

Witness's Signature

Date: **/**/____

Investigator's Signature

Date: **/**/____