

**A Study of the Efficacy of the
Postbiotic pA1c[®] HI as a
Metabolic Regulator in Healthy
Individuals With Hyperglycemia**

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PARTICIPANT INFORMATION SHEET, DATA PROTECTION AND INFORMED CONSENT

English translation of the Spanish text supplied

PROJECT INFORMATION

Project title: Study of the efficacy of the postbiotic pA1c@HI as a metabolic regulator in healthy individuals with hyperglycaemia.

Centre: Genbioma Aplicaciones.

Sponsor: Genbioma Aplicaciones S.L.

Principal investigator: Dr Deyan Yavorov Dayliev.

1. INVITATION AND PURPOSE

You are invited to participate in a study designed to evaluate the efficacy of a postbiotic nutritional supplement (pA1c@HI) on blood glucose control and the composition of the gut microbiota in people with glycated haemoglobin (HbA1c) $\geq 5.7\%$ and $< 6.5\%$ (prediabetes). Participation is voluntary.

2. WHY HAVE YOU BEEN INVITED?

You have been invited because you meet the initial criteria (HbA1c $\geq 5.7\%$ and $< 6.5\%$, age between 18 and 80 years, and clinical and therapeutic stability).

3. STUDY OBJECTIVE

To determine whether daily administration of one capsule of the pA1c@HI postbiotic product during the study period improves glycaemic control parameters and produces changes in the gut microbiota, and to collect evidence on safety and tolerability.

4. WHAT WILL YOUR PARTICIPATION INVOLVE? (SUMMARY)

The study will last approximately 12 weeks per participant and will include two main visits: baseline (pre-intervention) and final (post-intervention), with outpatient glucose sensor monitoring during specific periods, as well as two visits to a clinical laboratory for blood sampling and a mixed-meal tolerance test. During the study, you will be asked to:

- Sign the informed consent form.
- Wear a continuous glucose monitor (CGM), fitted by inserting a thin, flexible filament under the skin on the back of the upper arm. These sensors measure glucose levels and will be used at two points during the study: at the beginning and at the end, for two weeks on each occasion. For the sensor to work correctly, you will need to install the FreeStyle LibreLink app on your phone or mobile device and try to keep the device/phone close to the sensor so that continuous readings can be obtained.
- Take one capsule of the pA1c@HI postbiotic product (provided at the study centre) every day for 12 weeks.
- Collect and provide two stool samples.
- Attend Laboratorios de Análisis Clínicos Belén Perfecto for the blood draws required for blood tests and the mixed-meal tolerance test.
- Undergo two fasting blood tests (to measure glucose, HbA1c, insulin, GLP-1, lipid profile, liver markers and complete blood count) at the specified times. You will also undergo a mixed-meal tolerance test, which evaluates your body's response after consuming a standard meal and will take place at the clinical laboratory indicated. For this test, you will be asked to drink a nutritional shake (Ensure®), which will be provided to you. Blood samples will then be taken at 15, 30, 60 and 120 minutes to measure different blood parameters after ingestion. This type of shake contains a combination of nutrients representative of a standard meal (protein, carbohydrates, fats, minerals and vitamins), is freely available on the market, and occasional consumption has no contraindications in healthy individuals; however, it should not be used as a substitute for a balanced diet. Further information is available at <https://es.ensure.abbott/>.
- Complete questionnaires on eating habits, physical activity and gastrointestinal symptoms.
- Have body measurements taken (weight, height and circumferences) and have your blood pressure measured.

The exact details of visits, tests and the schedule are provided in the study protocol.

5. DURATION AND APPOINTMENTS

- Visit 1 (screening and baseline measurements): consent form signature, measurements, sensor placement before starting the product (14 days), and provision of the capsules and stool-sampling kit.
- Appointment during the two weeks before taking the product at a site of Laboratorios de Análisis Clínicos Belén Perfecto: fasting blood draw and mixed-meal tolerance test.
- Start of the intervention: after 14 days of pre-treatment sensor monitoring, daily supplementation begins and continues for 12 weeks.
- Final visit: sensor placement after taking the product, measurements and return of the stool-sampling kit.
- Appointment coinciding with the end of the intervention at a site of Laboratorios de Análisis Clínicos Belén Perfecto: fasting blood draw and mixed-meal tolerance test.

The study schedule would be as follows:

6. WHAT SAMPLES WILL BE COLLECTED?

- Two stool samples, which will be analysed to determine the composition of microorganisms (the microbiota) in the gut.
- Two complete fasting blood draws (approximately 12 mL per draw) for laboratory tests including glucose, HbA1c, insulin, GLP-1, lipid profile (total cholesterol, HDL cholesterol and triglycerides), liver transaminases (AST and ALT), and a complete blood count. In addition, as part of the mixed-meal tolerance test, a further eight blood samples will be collected in total after drinking the nutritional shake (four during the laboratory visit before starting the product and another four during the visit in the last two weeks of the intervention). For each mixed-meal tolerance test, samples will be taken at 15, 30, 60 and 120 minutes after drinking the shake. The purpose is to determine the participant's metabolic response to a meal by measuring GLP-1, glucose, insulin and C-peptide.
- Continuous glucose monitor data, for continuous measurement of interstitial glucose (download and analysis).
- Digital questionnaires on eating habits, physical activity and gastrointestinal symptoms (estimated total time: 20 minutes).

7. POSSIBLE RISKS AND DISCOMFORTS

- Blood draws: discomfort, possible bruising or brief dizziness.
- Continuous glucose monitor: this is a small device with a flexible filament inserted under the skin of the arm using an automatic applicator. Placement is quick. Possible discomforts include mild discomfort or brief stinging during placement, local redness or itching, or mild discomfort when it is removed. A silicone adhesive patch is also provided to keep the sensor in place during measurement periods, reducing the risk of it coming off and minimising discomfort from rubbing or sudden movements.
- Taking the product: the postbiotic has been formulated for safety and meets EFSA and FDA safety requirements. Mild gastrointestinal effects (e.g. gas or digestive changes) may occur. If adverse effects arise, they will be recorded and you will receive appropriate care. No additional specific risks beyond those associated with standard procedures in the protocol are anticipated.

If you experience any adverse effect during the study, you must contact the principal investigator or the study sponsor immediately (see the contact details on page 4 of this document). Such effects will be assessed and, if necessary, reported to the competent food-safety authorities (the Spanish Agency for Food Safety and Nutrition), in accordance with current regulations.

8. EXPECTED BENEFITS

You may benefit from improved blood glucose control; however, an individual benefit cannot be guaranteed. The scientific results will help advance strategies for preventing and managing metabolic disorders in the population.

9. INSURANCE AND COVERAGE

The study is covered by the sponsor's insurance policy, which covers harm and damages arising from participation in accordance with current regulations.

10. FINANCIAL COMPENSATION

Please note that you will not receive any financial compensation for participating in the study. Your participation will also not involve any additional expense or financial cost to you.

11. CONFIDENTIALITY AND DATA PROTECTION

Your consent is also requested for this research project in accordance with the requirements of European Data Protection Regulation 2016/679 and Spanish Organic Law 3/2018 of 5 December on Personal Data Protection and the guarantee of digital rights. Data will not be disclosed to third parties unless required by law. You are informed that you have the right to access, rectify and erase your data, and to restrict or object to its processing. Your consent is requested for the processing of your personal data for the purposes described above. If you have any questions, you may raise them with the study's principal investigator.

The data collected for the study will be identified by a code. Only the study doctor and collaborators will be able to link these data to you and your medical records. Your identity will therefore not be disclosed to anyone, except in certain circumstances, for example in a medical emergency or where required by law.

Only study data that do not contain information that could directly identify you—such as your first and last name, initials, address or social security number—will be transferred to third parties or other countries. Any such transfer will be for the same purposes as the study described here and will guarantee at least the level of confidentiality and protection required by the legislation in force in our country.

Access to your personal information will be restricted to the study doctor and collaborators, the Research Ethics Committee (REC), and personnel authorised by the study sponsor, when access is necessary to verify the study data and procedures. Confidentiality will be maintained in accordance with applicable legislation.

The data may be used in scientific publications in aggregated and anonymised form or in pseudonymised form (using codes that cannot be linked to the volunteers' identities). Rights of access, rectification and objection are described in the "Data Processing Consent" document. Study data may be used in future research related to the current study. The sponsor/investigator will take appropriate measures to protect your privacy and will not allow your data to be cross-referenced with other databases in a way that could identify you.

12. WITHDRAWAL FROM THE STUDY

Participation is voluntary. You may withdraw at any time without giving a reason; the healthcare you receive will not be affected. Data already collected up to the time of withdrawal may be used in the study in accordance with the applicable regulations and the information provided in the consent form.

13. CONTACTS AND QUESTIONS

If you have any questions, please contact:

- Principal investigator: Deyan Yavorov Dayliev — deyan@genbioma.com
- Study coordination (Genbioma / UPNA): participa@genbioma.com
- Study sponsor (Genbioma): josune@genbioma.com

This study has been approved by the Research Ethics Committee for Medicinal Products of the Chartered Community of Navarre.

PERSONAL DATA PROCESSING AND PROTECTION

1. IDENTIFICATION OF THE DATA CONTROLLER

The controller responsible for processing the personal and clinical data of volunteers participating in the efficacy study of Reglubetic-HI® for blood glucose control is:

Name or legal entity: GENBIOMA APLICACIONES, S.L.

Responsible person: Josune Ayo

Tax identification number (CIF): B71377428

Address: CEIN Office D3, Plaza Cein 5, Mocholí Industrial Estate, 31110 Noáin, Navarre, Spain.

Contact email: participa@genbioma.com

If you believe that your data protection rights have been infringed, you may submit a complaint to the Data Protection Officer's delegated unit in Navarre by emailing dpd@navarra.es.

2. PURPOSE OF PROCESSING

The purpose of processing volunteers' personal and clinical data is to:

- Conduct the study of the effectiveness of Reglubetic® for blood glucose control, with the aim of confirming the efficacy of the product developed by the company responsible for processing the data and collecting information on its mechanism of action.
- Prepare reports, publications and scientific communications on the study results, without identifying volunteers or disclosing data that could allow them to be identified directly or indirectly.
- Comply with the legal and administrative obligations arising from the study.

3. LEGAL BASIS FOR PROCESSING

- The volunteers' freely given, specific, informed and unambiguous consent, expressed by signing this document, in accordance with Article 6(1)(a) of the General Data Protection Regulation (GDPR, 27 April 2016) and Article 6.1 of Spanish Organic Law 3/2018 on Personal Data Protection (LOPD, 5 December 2018).
- The legitimate interests of the data controller, consisting of conducting the efficacy study, in accordance with Article 6(1)(f) of the GDPR and Article 6.2 of the LOPD.

4. CATEGORIES OF DATA

The personal and clinical data to be processed are:

- Identification data: first and last name, national identity document (DNI) or foreigner identity number (NIE), date of birth, sex, address, telephone number and email address.
- Health data: weight, height, body mass index, blood glucose level, eating habits, medical history, allergies, medication, adverse effects and any other data relevant to the study.
- Product-consumption data: date, time, dose, frequency and duration of administration.

5. DATA RECIPIENTS

Volunteers' personal and clinical data will not be disclosed to third parties unless there is a legal obligation or the volunteers have expressly authorised it. However, the following recipients may have access to the data:

- Personnel of the company responsible for processing, duly authorised and trained in data protection.
- The company's service providers acting as data processors and providing sufficient guarantees to implement appropriate technical and organisational measures to protect the data, in accordance with Article 28 of the GDPR and Article 33 of the LOPD.
- Competent authorities, where necessary to comply with a legal obligation or to protect the rights and legitimate interests of the data controller or the volunteers.

6. DATA RETENTION PERIOD

Volunteers' personal and clinical data will be retained for at least five years and for as long as necessary to fulfil the purpose of processing and the legal and administrative obligations arising from the study. Once the study has ended, the data will be blocked for the limitation period applicable to any liabilities that may arise from the processing, in accordance with Article 32 of the LOPD. Once that period has elapsed, the data will be permanently deleted.

7. VOLUNTEERS' RIGHTS

Volunteers have the following rights regarding the processing of their personal and clinical data:

- Right of access: to ask the data controller to confirm whether their data are being processed and, if so, to obtain information about them, including the purpose, recipients and retention period.
- Right to rectification: to request correction of inaccurate or incomplete data.
- Right to erasure: to request deletion of data when they are no longer necessary, when consent has been withdrawn, when the individual has objected to processing, when the data have been processed unlawfully, or when there is a legal obligation to erase them.
- Right to restriction of processing: to request that processing be restricted when the accuracy of the data is contested; when processing is unlawful and the individual opposes erasure; when the controller no longer needs the data but the volunteer needs them to establish, exercise or defend legal claims; or when the volunteer has objected to processing while it is verified whether the controller's legitimate grounds override those of the volunteer.
- Right to data portability: to request that the controller provide or transmit the personal data concerning them to another controller in a structured, commonly used and machine-readable format, where processing is based on consent or a contract and is carried out by automated means.
- Right to object: to request that the controller stop processing the data where processing is based on the controller's legitimate interests or on the public interest, unless the controller demonstrates compelling legitimate grounds for processing or the processing is necessary to establish, exercise or defend legal claims.
- Right not to be subject to automated individual decision-making: to request that decisions based solely on automated processing, including profiling, which produce legal effects or similarly significantly affect them not be applied to their data, unless necessary for entering into or performing a contract, authorised by law, or based on the volunteer's explicit consent.

These rights may be exercised by submitting a written request to the data controller, accompanied by a copy of the DNI or equivalent document, at the postal or email address provided in the controller identification section. Volunteers also have the right to lodge a complaint with the Spanish Data Protection Agency (AEPD) if they believe their right to data protection has been infringed.

8. WITHDRAWAL OF CONSENT

Volunteers may withdraw their consent to the processing of their personal and clinical data at any time, without affecting the lawfulness of processing based on consent before its withdrawal. To do so, they must notify the data controller in writing at the postal or email address provided in the controller identification section.

9. ADDITIONAL INFORMATION

Volunteers may request any additional information they consider necessary from the data controller regarding the processing of their personal and clinical data and may ask any questions they may have about it.

CONSENT DECLARATION

Consent to participate in the study "Study of the effectiveness of a postbiotic nutritional supplement".

I declare that I have read the Participant Information Sheet and the information concerning the processing of my personal and clinical data, and that I have had the opportunity to ask any questions I considered appropriate and to receive satisfactory answers from the person responsible for processing the data.

I also declare that I voluntarily agree to participate in the efficacy study described above and authorise the processing of my personal and clinical data for the purposes, under the conditions and with the safeguards set out in this document.

Please tick (✓) the appropriate option:

1. I agree to participate in the study: ☐ Yes ☐ No

2. I wish to be informed of clinically relevant findings arising from my participation: ☐ Yes ☐ No

3. I agree that data generated in this study may be used in future research related to the current study: ☐ Yes ☐ No

4. If data generated in this study are used for future research, I wish to be informed about the nature of those studies: ☐ Yes ☐ No

Participant details:

Name: _____

National identity document (DNI) / foreigner identity number (NIE): _____

Date: _____

Participant's signature: _____

Signature of the investigator who explained the study: _____

Date: _____