CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

An Open-Label, Acute Clinical Trial to Assess the Level of Ketone Production Following Consumption of Avela™ (R)-1,3-Butanediol in an Adult Population

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STUDY LOCATION(S): Home Study

STUDY SPONSOR(S): Genomatica Inc.

PROTOCOL NUMBER: CHSI-2101-02

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. Questions can be sent via e-mail either to the Research Associate or the Principal Investigator listed above, and answers to your questions will be sent to you via e-mail within 24 hours.

Study Purpose
The study is being completed to understand ketone production following the consumption of three beverage servings of Avela™, each providing 11.5 g of *(R)*-1,3-butanediol. Ketones are substances that your body can make if your cells don't get enough glucose (blood sugar). The study will also test whether the consumption of the product leads to any effects on gastrointestinal symptoms (symptoms that affect your stomach or digestive system) or alertness/sleepiness.

Study Procedures
If you choose to be in this study, the main study procedures include:

- Completion of questionnaires to determine if you experience any gastrointestinal effects or changes in your alertness/sleepiness and blood ketone analysis (using blood collected from the fingertips), using a blood ketone monitor. You will conduct these steps yourself and document the results using an online portal. Blood ketone analysis and completion of questionnaires will occur at several timepoints throughout the study, including at baseline (0 minutes), and at 30, 60, 90, 120, 180, 240, and 300 minutes.
- An Avela™ beverage will be consumed after the collection of the required information at the 0-, 30-, and 60-minute timepoints.
- At 240 minutes and after the collection of the required information, 1 ALOHA Organic Plant Based Protein Bar (Caramel Sea Salt) will be consumed.

You will be asked to enter your data electronically on a survey that was designed for this study. You will be able to access the website using a unique identification code that will be assigned to you. Your information collected on the website will be kept anonymous. ***Expected Duration***
You will be in this study for a single day and the study will be completed at your own home. The entire

study is expected to take a total of 5 hours, from start to finish.

Risks of Participation
The main risks of participation include possible bruising where blood will be taken using a small lancet [a fingerstick blood sampling tool]. It is possible that you will experience gastrointestinal discomfort [such as upset stomach, increased intestinal gas] or changes in mood [either increased energy levels of sleepiness or tiredness] following consumption of the study product. There may be additional risks which are currently unforeseeable.

Benefits to Participants
You will not directly benefit from participation in this study.

Benefits to Others or Society
This study will help researchers learn more about the levels of ketones produced following consumption of the study product.

Alternative Procedures or Treatments
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The study is being completed to understand the production of ketones, which is an alternate energy source than glucose for your body, following the consumption of three servings of Avela™, each providing 11.5 g of *(R)*-1,3-butanediol. The study will also evaluate whether the consumption of the product leads to any effects on gastrointestinal symptoms or alertness/sleepiness.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 30 participants (males and females) will take part in the research study.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; utilizing an online questionnaire, the study team will verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you are a healthy adult (age 18 to 65 years of age, with a body mass index of 18 to <35.0 kg/m^2 and you weigh more than 110 lbs).

Exclusion Requirements
You cannot participate in this study if you have experienced recurring gastrointestinal issues in the past 6 months or, if you are pregnant, breastfeeding or you have a medical condition affecting your pancreas, liver, thyroid or gall bladder.

HOW LONG WILL THE STUDY GO ON?
This study is completed within 1 day and takes about 5 hours to complete.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to complete a “screening” process, which will help researchers decide if you meet the eligibility criteria for study participation. The screening procedures include a series of questions to ensure that you meet the inclusion/exclusion criteria.

During the main part of the study...

If you are eligible to participate in the study, and you choose to take part, then you will complete the following procedures:

- Signing of an informed consent form;
- Discussion with your primary care doctor prior to the study start to review your enrolment in the clinical study;
- Overnight fast;
- If you are a female, who is not post-menopausal [defined as not having had a period for 12 consecutive months or longer] or you have not had any procedure that would result in you not being able to have children, such as "tying of tubes" or a removal of your ovaries, you will be asked to take a pregnancy test on the day of study;
- Completion of questionnaires to assess gastrointestinal symptoms and alertness/sleepiness ((a total of 8 measures over a 300-minute period, including at 0, 30, 60, 90, 120, 180, 240 and 300 minutes);
- Measures of blood ketone levels using a lancet (finger-stick blood sampling tool), ketone meter, and ketone test strips (a total of 8 measures over a 300-minute period, including at 0, 30, 60, 90, 120, 180, 240 and 300 minutes);
- Consumption of 3 servings of Avela™, each providing 11.5 g of *(R)*-1,3-butanediol (at 0, 30, and 60 minutes);
- Consumption of 1 ALOHA Organic Plant Based Protein Bar (Caramel Sea Salt) at 240 minutes; and
- Uploading of study results, electronically.

After you complete the main part of the study, you will have completed the requirements of the study.
There is no follow-up visit required once the study is completed.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
You may have gastrointestinal side effects, such as upset stomach or increased intestinal gas while in the study. Many side effects go away soon after you stop taking Avela™ *(R)*-1,3-butanediol

You should talk to the research team about any side-effects you experience while taking part in the study.

Risks and side effects related to the study protocol include those which are:

Likely
- Slight bruising of the fingertip, where capillary blood is acquired using a lancet.

Less Likely
- Possible gastrointestinal effects (such as upset stomach, increased intestinal gas) or changes in mood (either increased energy levels, or sleepiness and tiredness) following consumption of the study product.

Rare but serious
- None

Consumption of Avela™ in this study may involve risk to the subject which is currently unforeseeable.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation
All participants will be provided with a Keto-Mojo ketone/glucose monitor kit (complete with lancets, alcohol swabs, bandages, a sharps container and ketone test strips); a measuring tape; a shot glass with the Avela™ logo and a duffel bag, which they are permitted to keep, following the study.

Reimbursement
As the study is being conducted at your own place of residence, there will not be any out-of-pocket expenses, such as parking or transportation fees; you should not incur any additional costs. As such, you will not receive any reimbursement.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no cost to you for your participation in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
Based on other studies conducted with a similar investigational product, it is not expected that there is any risk of injury from its consumption. Moreover, the investigational product is a lawful food ingredient in the United States; it is Generally Recognized as Safe at its intended uses and use levels in the clinical trial. If, however, you develop complications or injuries as a result of participating in this research study, you will be responsible for seeking immediate medical care. Compensation will not be provided for injury incurred during the clinical study. Some insurance companies may not cover costs associated with clinical research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay. Furthermore, it is imperative that you promptly tell the researchers if you believe you have suffered an injury from participation in the clinical trial by contacting the Research Associate or Principal Investigator listed at the top of this form.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately by contacting the Research Associate or Principal Investigator listed at the top of this form**. The research team may also end your participation in this study if you do not follow instructions, the study sponsor decides to stop the study, or your safety and welfare are at risk.

If you experience any gastrointestinal side effects, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, you should discard unused study product.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
The protection of your confidentiality is of the utmost importance to Genomatica. No information that compromises your identity will appear on any of the study forms. The only documents that will contain you name are the consent form that you will be asked to sign prior to engaging in the study, as well as the Master Subject Listing, which matches each participant, by name, to the unique identification code that they are assigned. Study results will be stored in a locked filing cabinet at 4757 Nexus Centre Drive, San Diego CA 9212 until the study is complete, at which point these and the other study-related documents will be stored securely (see Data Storage). Your personal study results will not be shared with you.

Data Storage

The study-related forms, consent forms, and the Master Subject Listing, will be kept in one box for all the study participants; the box will be labeled with the protocol title, protocol number, and Institutional Review Board (IRB) number. The box will be sealed with tamper-proof tape and will be stored in a locked filing cabinet at 4757 Nexus Centre Drive, San Diego CA 9212 for a retention period of 2 years, at which point the contents of the box will be destroyed.

Data Retention
Information will be retained for 2 years, counted from the day the last subject completes their participation in the study.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible, though highly unlikely, that an unauthorized person might see it. Total privacy cannot be guaranteed.

Future Research Use

Researchers will use your information to conduct this study. Information gathered during this research study will only be used for this study. It will not be shared with other researchers.

ClinicalTrials.gov
ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a description of the clinical trial protocol and a summary of the results. You can search this Web site at any time

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the Research Associate or Principal Investigator listed at the top of this form.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the IRB at support@pearlirb.com.

What is an IRB? An IRB is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered to your satisfaction by the Research Associate or Principal Investigator listed at the top of this form. If you agree to sign the consent form, you will take a photo of the signed page and send it to the Research Associate by e-mail (listed on the first page of this consent form). You will keep a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights". **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship or your career with Genomatica Inc.

If, during the study, important new information becomes available that may affect your willingness to continue to participate, this information will be provided to you by the Research Associate listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	

Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures are different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the Research Associate at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the support@pearlirb.com.