UNIVERSITY OF MARY HARDIN- BAYLOR
School of Exercise & Sport Science

Title of Investigation: Effects of Lactobacillus Acidophilus MPH734 on Acute, Subacute, and Sustained Lactose Tolerance in Healthy Adults

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Sponsor: Manzo Pharmaceuticals, LLC (Shohola, PA)

Description of the Study:
I will be one of about 90 apparently healthy males and females between the ages of 18-55 to participate in this study. During my first appointment in the Human Performance Lab (HPL), I will be given a verbal and written explanation of the study requirements, and sign an informed consent statement that complies with the University of Mary Hardin-Baylor. I will also fill out other forms that are required for me to participate and a lab staff member will review my paperwork to determine if I can participate. If I am cleared to participate in the study, I will be familiarized to the testing procedures. I will be told that I will need to make a total of at least six (6) visits to the lab with only five (5) of those involving testing

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over the span of a 15-week period. I will complete one initial laboratory test followed by one week of consuming either a low or high dose of a probiotic supplement or a placebo. I will be retested at the end of the first week, and then will undergo laboratory testing again at 30, 60, and 90 days subsequent the first week. During my time outside of the HPL I will perform weekly testing at home. Once I complete the familiarization session, I will be scheduled for all testing sessions. Before every testing session I will follow the 24-hour restricted diet protocol and be fasted for 12 hours. I will complete weekly nutrition logs throughout the duration of the study and during the one week prior to my initial laboratory test.

I will participate in testing sessions at the beginning of the study (T1). After one week of treatment, the second testing session will occur (T2). Midway through the one week of treatment, I will perform an at-home symptoms test. After the second testing session is finished I will stop taking the supplement for one month and will do weekly at-home symptoms testing. After thirty days I will come in for testing session three (T3). I will repeat the monthly sessions two more times (T4-T5).

I will arrive to my first testing session 12-hours fasted, after adhering to a 24-hr restricted diet protocol. I will be weighed, I will urinate into a cup, I will have my blood pressure and heartrate measured, I will have my blood drawn, I will rinse my mouth with a non-alcohol rinse, I will breath into a handheld machine, I will take one of the three possible supplements, I will consume 25 grams of purified lactose sugar, I will repeat breathing into the handheld machine at the end of each hour for three hours, and I will fill out a specific symptoms questionnaire. I will repeat these steps for each testing session (T1-T5). Each testing session will last approximately 3.5 hours.

I understand taking the supplement is required to participate in the study. I understand that if clinically significant side effects are reported, I will be sent to discuss the problem with Dr Chris Lockwood, the Principal Investigator of this study at the University of Mary Hardin-Baylor. I may be told to discuss the matter with my doctor to see whether any medical treatment is needed and whether I can continue in the study.

Inclusion Criteria

- Participants will be male or female between the ages of 18-55 years;
- Participants will be apparently healthy and free from disease, as determined by a health history questionnaire;
- Participants will not be excluded if he or she has been clinically diagnosed with a carbohydrate malabsorption disorder, or is or has been prescribed to take prescription or over-the-counter medication for such;
- Participant has self-diagnosed or otherwise avoids consuming dairy, lactose, and other dairy-containing products, or regularly consumes Lactase enzymes for digestive support;
- Participant agrees and can comply with the study protocol;
- Participant provides signed and dated informed consent to participate in the study.

Exclusion Criteria

- Participant is or may be pregnant, is trying to become pregnant, or is breastfeeding;
- Participant currently uses, or has discontinued the use of nicotine-containing products within twelve (12) months of the start of the study;
- Participant lives or works within an environment that chronically exposes the subject to second-hand smoke;

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- Participant currently uses, or has discontinued the use of recreational drugs or medicinal marijuana within twelve (12) months of the start of the study;
- Participant has been clinically diagnosed with a digestive disorder such as gastrointestinal disease, chronic diarrhea or constipation, irritable or inflammatory bowel syndrome, Crohn's disease, or is, or has been prescribed to take prescription or over-the-counter medication for such;
- Participant has ever undergone gastric bypass surgery, or has undergone an abdominal or other gastrointestinal surgery within twelve (12) months of the start of the study;
- Participant is taking, or has taken antibiotic medications within two (2) weeks of the start of the study;
- Participant has undergone a colonoscopy within two (2) weeks of the start of the study, or is scheduled to receive a colonoscopy during the study;
- Participant has undergone a barium study or received an enema within two (2) weeks of the start of the study, or is scheduled to, or receives such during the study;
- Participant is taking, or has taken probiotics within two (2) weeks of the start of the study;
- Participant uses lactose digesting enzymes during the study;
- Participant is taking, or has taken weight loss, prebiotic [e.g., fructo- or galacto-oligosaccharides (FOS or GOS), psyllium, or insulin fiber, etc.], or laxative / stool softener dietary supplements, over-the-counter, or prescription medications within two (2) weeks of the start of the study;
- Participant is allergic to any ingredient present within the dietary supplement or placebo treatment;
- Participant reports any unusual adverse events associated with this study that, in consultation with the study investigators or the participant's doctor recommends removal from the study;
- Participant fails to comply with the study protocol.

I understand that I have completed all documents required of me and have reported all information related to my health status and health history to the best of my knowledge. I furthermore understand these documents will be used to determine if I qualify for the study.

Risks and Benefits

I understand that the ingredients in the supplements that I will take are currently available over the counter nutritional supplements and approved food additives sold in the United States. I understand that the FDA has not evaluated the safety or marketing claims of these nutritional supplements; only that each ingredient present within the supplements are approved for human consumption as food additives or generally recognized as safe (GRAS).

I also understand that I may experience some stomach discomfort associated with the lactose sugar challenge I will be required to consume for participation in the study. I may also feel discomfort during the blood draw. I am aware that I can stop participating in the study at any time, including if any of these feelings of discomfort become too much.

If an adverse event does occur, standard reporting protocol will be enacted. If necessary, lab staff will check for vital signs and begin any necessary interventions while another researcher contacts 911 emergency and UMHB's campus police at extension 5555.

I understand that trained, HPL lab staff will supervise all testing sessions. I understand that a telephone and an automated electronic defibrillator are behind the front desk of the Mayborn Campus Center in case of any emergencies and that there will be no less than two researchers working with me during each

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testing session. I understand that emergency procedures are posted in the lab in the unlikely event that any emergency may arise.

Alternative Treatments
This is not a medical treatment. Therefore, if medical treatment is needed, I must continue to obtain treatment for any medical problem I might have from my personal physician.

Costs and Payments
No academic credit will be given for participating in this study. I understand that if I am an intercollegiate athlete I may not be eligible to receive payment to participate in this study. I understand that compensation will be broken down as receiving $105 after completing the first leg (month) of the study (after T3 testing); $85 after completing the second leg (month) of the study (after T4 testing); and $85 after completing the third leg (month) and I have turned in all the required documents after the study (after T5 testing).

New Information
Any new information obtained during the course of this research that may affect my willingness to continue participation in this study will be provided to me. In addition, I will be informed of any unusual/abnormal clinical findings in which medical referral to my personal doctor may be warranted. If I desire, I may request that this information be provided to my doctor.

Confidentiality
I understand that any information obtained about me in this research, including questionnaires or medical history will be kept confidential to the extent permitted by law. However, I understand in order to ensure that FDA regulations are being followed, it may be necessary for a representative of the FDA to review my records from this study which may include questionnaires, medical history, laboratory findings/reports, statistical data, and/or notes taken about my participation in this study. In addition, I understand that my records of this research may be subpoenaed by court order or may be inspected by federal regulatory authorities. I understand that data derived may be used in reports, presentations, and publications. However, I will not be individually identified. Additionally, I understand that confidentiality will be maintained by assigning code numbers to my files, access to data will be limited to research assistants and study investigators, my identifiable information and subject data file will be stored in locked cabinets, and that access to computer files will be limited to authorized personnel only and password protected.

Right to Withdrawal
I understand that I am not required to participate in this study and I am free to withdraw from the study at any time. Further, that my decision to withdraw from the study will not cause a loss of benefits to which I might be otherwise entitled.

Compensation for Illness or Injury
I understand that if I am injured as a direct result of taking part in this study, I should consult my personal doctor to obtain treatment. I understand that the cost associated with the care and treatment of such injury will be the responsibility of me or my insurance carrier. In some cases, insurers may not reimburse claims submitted for a research-related injury resulting from medical procedures or treatments performed as part of a research study. I understand that the University of Mary Hardin-Baylor, the investigator's institutions, and the grant sponsor will not be accountable for illness or injury acquired during the course of this study.

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Statement on Conflict of Interest
I understand that researchers involved in collecting, analyzing, and interpreting data for this study have no financial or personal interest in the outcome of the results of this study, nor are any of the researchers currently receiving, or have previously received personal compensation from the sponsor of this study.

Voluntary Consent
I certify that I have read this consent form or it has been read to me and that I understand the contents and that any questions that I have pertaining to the research have been, or will be answered by Chris Lockwood, Ph.D. (Assistant Professor, School of Exercise and Sports Science, Human Performance Lab, UMHB Box 8010, 900 College Street, University of Mary Hardin-Baylor, phone: 254-295-5036, CLockwood@umhb.edu) or one of the research associates. My signature below means that I am at least 18 years of age and that I freely agree to participate in this investigation. I understand that I will be given a copy of this consent form for my records. If I have any questions regarding my rights as a research participant in this study I may contact Dr. Aaron Baggett, Chair of Institutional Review Board (phone: 254-295-4553, abaggett@umhb.edu) at UMHB.

Date _____Participant's Signature _____

I certify that I have explained to the above individual the nature and purpose of the potential benefits and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

Date _____Investigator's Signature _____

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