Informed Consent and Patient Information

Title:

Development of a Preparation for Supportive Supplementation of Probiotics in Patients with Reflux

A two-arm, double-blind, randomized, placebo-controlled study investigating the efficacy of a probiotic preparation developed as supportive supplementation of probiotics in patients with reflux

Study ID: FW10010127
NCT Number: * to be added

Date: 2026-04-24

Patient Information

Dear Patient,

Your attending doctor has offered you participation in a clinical trial of the product *GastroWell*. This is a duly approved dietary supplement containing a mix of probiotic bacteria, designed on the basis of the most up-to-date scientific knowledge, specifically for use in adult patients with gastroesophageal reflux disease (GERD) taking proton pump inhibitors (PPI). The study is double-blinded, meaning that during the study you may be assigned to a control group taking placebo (i.e., a product without active ingredients), and neither you nor your doctor will know whether you are receiving the active product GastroWell or the placebo.

The expected benefit of the product is the minimization of undesirable changes in the gut microbiota, thereby alleviating reflux symptoms and improving quality of life. Your participation in the study is short-term: the investigational product will be administered for 6 weeks. The dosage is two tablets twice daily – in the morning on an empty stomach before the first meal, and in the evening after a meal. To assess the effect of the product, your health will be regularly monitored and recorded during hospitalization using standard clinical methods. This includes a follow-up gastroscopy (already recommended before study enrollment) and a clinical examination by a physician. The study will evaluate changes (before study initiation and after the experimental phase) in the diversity and composition of the bacterial community, as well as the quantification of probiotic strains from the preparation in stool samples and oral mucosa swabs.

Although the investigational product is considered safe, its use may bring some potential risks. These risks may include hypersensitivity reactions to product components such as diarrhea, bloating, or other gastrointestinal discomfort. These adverse effects are rare, and therefore your participation in the clinical trial is not expected to involve excessive risks. If there is any suspicion of an inadequate response for any reason, administration of the product will be discontinued. The study sponsor, MicroCen Trans s.r.o., is responsible for participant safety and for any damages related to participation in this research study. The study is properly insured in accordance with applicable legislation. The investigational product is duly notified. In case of health complications, please contact us immediately at +420 770 132 996 (RNDr. Petr Ryšávka, Ph.D.) or +420 588 445 308 (MUDr. Vít Navrátil, Ph.D.). More detailed information on compensation options will be provided by the sponsor upon request.

Your participation in this clinical trial is voluntary and may be terminated at any time. No financial compensation is provided for participation; however, the capsules with the investigational product or placebo will be supplied free of charge.

By signing this document, you confirm that you will take the product conscientiously and responsibly. By signing, you also agree that the sponsor or its authorized representative may contact you by phone at the end of the supplementation period to complete a questionnaire. The provision of personal data will be fully in accordance with the requirements of the GDPR.

Informed Consent of Patient for Participation in Clinical Trial

Study Title: A two-arm, double-blind, randomized, placebo-controlled study investigating the efficacy of a probiotic preparation developed as supportive supplementation of probiotics in patients with reflux

Patient name:
Date of birth:
Patient study number:
Responsible doctor:

1. I, the undersigned, agree to participate in this study.
2. I have been fully informed about the objectives of the study, its procedures, and what is expected of me. The physician responsible for the study explained the expected benefits and potential health risks that may occur during my participation and explained how adverse events will be managed. I acknowledge that this study is a research activity.
3. I have informed the study physician of all medications I have taken in the last 28 days and those I am currently taking. If another physician prescribes me a new medication, I will inform them of my study participation and will not take the medication without the study physician's consent.
4. I will cooperate with my physician during treatment and will immediately report any unusual or unexpected symptoms.
5. I understand that I may interrupt or withdraw from the study at any time without affecting my further treatment. My participation is voluntary.
6. Upon enrollment, my personal data will be stored with full confidentiality protection in accordance with Czech law. With my consent, representatives of the sponsor, independent ethics committees, and national or local competent authorities (in the Czech Republic, the State Institute for Drug Control) may access my medical records for verification. Confidentiality of my personal data will be guaranteed. For the purposes of the study, personal data may only be provided to other parties in anonymized form under a code number. For research and scientific purposes, my data may also be provided in anonymized form or with my explicit consent.
7. No financial compensation is associated with my participation.
8. I understand that my name will never appear in reports of this study. I will not object to the use of the study results.
9. I have received a signed copy of this informed consent.

Patient signature:
Date:

Study doctor signature:
Date: