Synopsis and Protocol Summary of Clinical Study

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

Synopsis of Clinical Study REFLUX

Protocol summary in English language

Project Code:

FW10010127

Project Title:

Development of a preparation for supportive supplementation of probiotics in patients with reflux

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.

Justification for the proposed clinical trial:

Esophageal reflux, also known as gastroesophageal reflux disease (GERD), is a common condition affecting many adults worldwide. There is evidence that changes in the gut microbiome may influence the symptoms and severity of GERD. Probiotics, capable of restoring balance in the gut microbiota, may provide significant relief from GERD symptoms. This study is designed to assess the efficacy of a probiotic dietary supplement in reducing the adverse effects of GERD, which are also associated with proton pump inhibitor (PPI) therapy.

Risk/benefit assessment:

Based on a literature review, probiotic use is generally safe and may provide clinical benefits to patients with gastrointestinal problems. Potential risks associated with the administration of bacterial strains, such as infections in immunocompromised patients, are carefully monitored and minimized through the selection of specific probiotic strains. The benefits include alleviation of GERD symptoms and improved quality of life. Throughout the study, participant safety will be monitored, and all adverse events will be documented and evaluated.

Investigational product:

A probiotic dietary supplement containing a blend of probiotic bacteria from the Lactobacillaceae family, and the genera Streptococcus and Bifidobacterium, selected based on the latest knowledge concerning the use of probiotics in relation to GERD.

Composition of the probiotic preparation:

- **Active ingredients:**
  - *Lactiplantibacillus plantarum* LP-ONLLY
  - *Ligilactobacillus salivarius* LS33
  - *Streptococcus salivarius* SAL21
  - *Bifidobacterium animalis* subsp. *lactis* HN019
  - Guar gum
  - Extract from the husk of flaxseeds (*Linum usitatissimum*)
- **Excipients:**
  - Soluble corn fiber
  - Flavoring
  - Steviol glycosides
  - Silicon dioxide
  - Magnesium stearate

Placebo: Placebo tablets contain only the excipients of the dietary supplement.

Number of study subjects:

50 subjects will be enrolled (25 patients supplemented with probiotics and 25 patients receiving placebo).

Purpose of the clinical trial:

The objective of this trial is to evaluate the effect of the probiotic dietary supplement on the diversity and composition of the gut microbiome in patients diagnosed with GERD who are on PPI therapy. The study will also monitor changes in the oral microbiome and the impact of probiotic supplementation on patient quality of life and GERD symptoms.

Study design:

The proposed clinical trial is randomized and double-blinded. It has two arms:

1. Patients supplemented with the probiotic preparation.
2. Patients receiving placebo.

Subjects will be randomized to ensure that neither patients nor physicians know who is receiving probiotics and who is receiving placebo.

Indication:

The dietary supplement is intended for patients diagnosed with GERD. The aim of supplementation is to minimize dysbiosis in the gastrointestinal tract caused by the disease itself and/or pharmacotherapy, to reduce reflux-related symptoms, and to improve the quality of life of GERD patients.

Objectives:

- **Primary endpoint:**
  - Minimization of dysbiosis in the gastrointestinal tract caused by the disease itself and/or pharmacotherapy.
- **Secondary endpoints:**
  - Reduction of GERD symptoms assessed by standardized questionnaires and changes in symptom scores.
  - Improvement of quality of life assessed by specific questionnaires.
  - Evaluation of safety and tolerability of the preparation.
  - Reduction of gastrointestinal discomfort.

Study population:

- **Inclusion criteria:**
  - Adults aged 40–55 years.
  - Diagnosed GERD.
  - Consent to participate and signed informed consent.
  - Stable health without current complications.

  - Patients on stable pharmacological PPI therapy (rabeprazole).
- **Exclusion criteria:**
  - Concurrent participation in another clinical study.
  - Use of probiotics or prebiotics within the last 4 weeks.
  - Pregnancy or breastfeeding.
  - Systemic antimicrobial therapy within the last 4 weeks.
  - Infectious disease of the respiratory or gastrointestinal tract within the last 2 weeks.
  - Serious chronic disease that could affect study results, including cancer, diabetes, inflammatory bowel disease, diagnosed SIBO.
  - Prior surgeries, especially fundoplication and resections of the esophagus or stomach.
  - Patients with psychiatric or cognitive disorders.
  - Hypersensitivity to components of the investigational product.

Supplementation:

Patients will take the probiotic preparation, 2 tablets twice daily (morning before meals and evening after meals). The experimental phase will last 6 weeks. Patients in the control arm will receive placebo. Supplementation will be discontinued if adverse effects occur.

Statistics:

Paired comparison of diversity and composition of the microbiome, as well as quantification of probiotic strains from the preparation before the start of the study and after the experimental block, will be conducted using stool samples and oral swabs. Questionnaire results and clinical measurements (endoscopic examination) will be evaluated and correlated with laboratory findings. Comparisons will also be made between the probiotic and placebo groups. A detailed statistical plan will be included in the study protocol.

Study plan and schedule:

- Study initiation: Week 1
- Experimental phase: 6 weeks
- Follow-up evaluation: Immediately after supplementation ends

Safety monitoring:

During the study, adverse events and the safety profile of the probiotic product will be regularly assessed. All serious adverse events will be thoroughly investigated and evaluated.

Conclusion:

This study is designed to assess the potential benefits of probiotic dietary supplementation in GERD patients. The results may contribute to a better understanding of the role of probiotics in GERD management and to the development of new therapeutic strategies.