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ÖREBRO UNIVERSITY

Örebro University

SCHOOL OF MEDICAL SCIENCE

Nutrition-Gut-Brain Interactions Research Centre (NGBI)

STUDY WITH TITLE:

"Towards a food ingredient clinically proven to benefit gut health: novel RG-I variants"

STUDY PROTOCOL

The plant cell wall derived RG-I (from chicory or carrot) and maltodextrin (placebo) in capsuled form will be provided by the food company NutriLeads B.V (Wageningen, The Netherlands), which has run tests of safety of the products and warranties their food grade quality and safety. The administration of RG-I will be done via a human intervention study of parallel arms, randomized, placebo – controlled, double blinded design (proof of concept study).

Task 1: Evaluation of the prebiotic and intestinal inflammatory effects of RG-I daily supplementation
The dietary fibre from different RG-I sources will be tested for its prebiotic and immunomodulatory potential. Thus, the effects of these fibres on short chain fatty acid (SCFA) profile, microbiota composition, microbiota-associated metabolites and intestinal inflammatory markers will be investigated.
In this Task, quantification of the aforementioned parameters will be performed in fecal samples which will be obtained from the study participants every week during their participation in the study. Furthermore, for this purpose subjects will complete questionnaires related to their diet; Food Frequency Questionnaire (an extract of the online tool that will be used for this purpose and a Gastrointestinal Symptom rating scale (GSRS) in the beginning and in the end of the interventional period.

Task 2: Evaluation of the immunomodulatory, gut-brain interaction and lifestyle related effects of RG-I daily supplementation

The dietary fibre from different RG-I sources will be tested for their immunomodulatory and lifestyle related effects. The effects of fibres on immune activation markers related peptides markers will be investigated from blood samples collected from the study participants. Furthermore, to assess the effects of RG-I supplementation in lifestyle, subjects will complete questionnaires related to their physical activity (IPAQ) and quality of life (EQ-5D-5L) at the beginning and at the end of the interventional period for this Task.

STATISTICAL ANALYSIS

The groups will be of equal size and a time dependent analysis will be performed using a logistic generalized estimating equations (GEE) model via a stepwise approach. age, gender and BMI will be included AS confounding parameters. As fixed factors group (treatment versus placebo: dummy variable), time, time squared and the interaction between group and time will be taken into account. When the outcome does not warrant a GEE approach a Chi square analysis with expectation will be performed. Calculations will be done for a two-sided statistical evaluation at a significance level of 0.05.