Impact of Consumption of Beta-glucans on the Intestinal Microbiota and Glucose and Lipid Metabolism

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STUDY PROTOCOL

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Introduction

Metabolic syndrome (MS) is a complex lifestyle disease manifesting metabolic disorders such as abdominal obesity, dyslipidemia, hyperglycemia and hypertension. There are many studies reporting how gut microbiota correlates with metabolic disorders or contributes to the development of obesity trough increased energy harvest. An increasing interest in finding the diet that could regulate the composition of gut microbiota and consequently improve the individual conditions related to some of the metabolic disorders, exists. The aim of our study will be to investigate, whether consumption of barley beta glucans can positively modulate the composition of gut microbiota and metabolic parameters related to MS. Barley beta glucans are polysaccharides found in kernel endosperm and improve both lipid and glucose metabolism. The effects of barley beta glucans on gut microbiota composition are still poorly investigated in human clinical trials.

We will perform a double-blind, placebo controlled, randomized clinical trial with volunteers diagnosed with MS. The exact study protocol and procedure will be explained to the participants, who will meet inclusion criteria. After assignment of participation agreement, participant will be randomized and allocated to test or placebo group. Before and after the dietary intervention, anthropometric measurements, blood analysis, including oral glucose tolerance testing (OGTT), and fecal sampling will be performed. Participants will daily complete food frequency questionnaire and detailed 72-hour dietary recall. During intervention participants will daily consumed test bread with added 6g beta glucans or bread without added beta-glucans.

The study was approved by the Republic of Slovenia National Medical Ethics Committee (112/08/13).

Study protocol

A) Participants information and inclusion criteria

Name	
Surname	
Age	
Body height & body weight (cm, kg)	
Diabetes type 2	
Kidney disfunction	
Thyroid disfunction	
Treatment for hypercholesterolemia (not hypertension)	
Total cholesterol (mmol /l)	
Body Mass Index (BMI)	

B) Before and after intervention: Blood test Analysis and Anthropometric measurements

1. Lipid profile, Anthropometric measurements

Parameter	Before dietary intervention	After dietary intervention
Total cholesterol (mmol/l)		
LDL-cholesterol (mmol/l)		
HDL-cholesterol (mmol/l)		
Triglycerides (mmol/l)		
Blood pressure (mmHg)		/
Body weight (kg)		
Body waist (cm)		

2. Oral glucose tolerance test (OGTT)

Sampling time after glucose consumption (min)	Before dietary intervention		After dietary intervention	
	Glucose level (mmol/l)	Insulin level (µU/ml)	Glucose level (mmol/l)	Insulin level (µU/ml)
0				
30				
60				
120				

3. Gut microbiota analysis and short chain fatty acids measurements

Faecal samples will be obtained before and after dietary intervention.

Analysis of gut microbiota composition will be performed followed DNA extraction, with several methodologies; Denaturing Gradient Gel Electrophoresis (DGGE), qPCR, new generation sequencing (illumine Miseq platform).

Short-chain fatty acids determination

Short-chain fatty acid	Before dietary intervention (g/kg)	After dietary intervention (g/kg)
Butyric acid		
Acetic acid		
Propionic acid		

4. 72-hour dietary recall

Dietary recall will be performed three times before and during dietary intervention to obtain average nutrient intake:

Average nutrition intake per 100 g	**Before dietary intervention**	**Between dietary intervention**
Energy (kcal)		
Protein (g)		
Fat (g)		
Total carbohydrates (g)		
Total dietary fibre (g)		
Water (g)		