Title:

Development of Continuous Glucose Monitoring System Cohort for Personalized Diabetes Prevention and Management Platform

NCT number: NCT04369833

Document date: 2020.11.15

Study Protocol

① Subject's demographic information and medical history survey

② Physical examination/measurement information and body composition analysis information

- Body composition analysis using InBody body composition analyzer

③ Acquisition of metabolic-related basic clinical laboratory tests and measurement results

- Can be replaced with test results 3 months prior to registration,

- If there is no test result, it is measured using a blood sample on the day of the oral glucose tolerance test.

- Arteriosclerosis test and bone mineral density test: use test results 3 months prior to registration

④ Insertion/removal of continuous glucose monitoring system device and collection of glucose data

– Using a professional continuous glucose measuring system (iPro2 professional CGM, Medtronic® , CA, USA), continuous glucose data is collected for 7 days of the subject at 5-minute intervals

- The sensor is inserted on day 1 and removed on day 7 by a medical professional

- Education on precautions according to sensor insertion on day 1

⑤ Oral glucose tolerance test

– Visiting hospital with fasting for at least 8 hours during continuous glucose measurement

- After ingesting 75g glucose, blood glucose and insulin values are measured through blood collection (0, 30, 60, 90, 120 minutes)

⑥ Standard meal intake

– Standard meal with accurate calorie and carbohydrate intake (500 Kcal)

- Delivery standard meal to the subject's home in the morning (day 2-5)

⑦ Food intake information

– Collect information on a variety of foods consumed, including standard meals consumed during continuous glucose measurement

- Transmitted through pictures before/after food intake

- Analyze nutritional information using the CanPro 5.0 Professional Program

⑧ Activity/Sleep/Heart Rate Information

– Smart band (Fitbit Inspire HR, Fitbit® , CA, USA) during continuous glucose measurement

- Collect various physical information such as the subject's activity, sleep and heart rate

⑨ Intestinal microbial analysis

- One stool is collected at home during the study period

Statistical Analysis Plan

: Descriptive statistics are obtained for the subject's demographic data and health status.

In the case of continuous data, the mean, standard deviation, median, minimum, and maximum are calculated, and for categorical variables, the frequency is calculated.