The Efficacy of Glucerna SR in Chinese Drug-naïve Subjects With Type 2 Diabetes

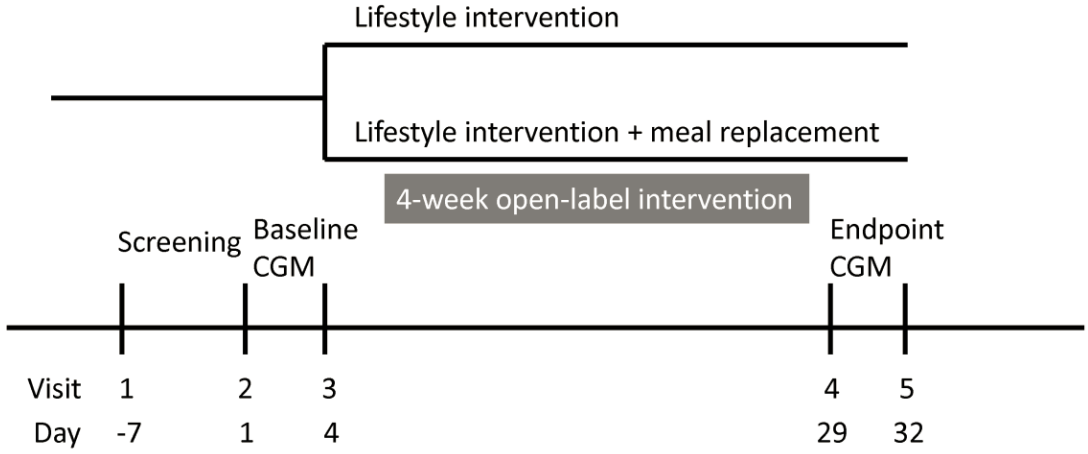
Study Protocol and Statistical Analysis Plan

NCT：02248714

Date: 2018.12.31

Study Protocol:

Following study enrolment (visit 1), each subject underwent a 75-g oral glucose tolerance test (OGTT). Participants who met the eligibility criteria were then continuously monitored for 72 hours (visit 2 to visit 3) with a retrospective continuous glucose monitoring (CGM) system (Medtronics, Northridge, CA). After 3 days of CGM (visit 3), the subjects were randomized (1:1) to receive either study group or control group for 4 weeks. Participants in the study group were instructed to replace breakfast with Glucerna SR (Abbot Nutrition) powder 52 g dissolved in 200 ml of warm water and both groups received lifestyle education. At the end of the 4-week intervention, subjects underwent another CGM from visit 4 (Day 29) to visit 5 (Day 32), at which a final OGTT in the fasting state was conducted. The schematic outline of study conduction is illustrated in the figure below.



The incremental area under the curve of postprandial blood glucose (AUCpp) during CGM was calculated as the area between the glucose concentration-time curve, and the pre-prandial baseline glucose value measured at 4 h after each meal. Intra-day glycaemic variability (GV) parameters include the standard deviation of blood glucose values (SDBG), glucose coefficient of variation (CV), and the mean amplitude of glycaemic excursions (MAGE). CV was calculated by dividing the SDBG by the mean of the corresponding glucose readings. MAGE was calculated as the arithmetic mean of the differences between consecutive peaks and nadirs. Only excursions of more than

1 SDBG of the mean glycaemic values were considered for the calculation of MAGE.

Anthropometric and biochemical parameters were measured at visit 1 (baseline) and visit 4 (post-intervention). Body mass index (BMI) was calculated as the weight (kg) divided by squared height (m). Blood pressure (BP) was measured twice using a standard mercury sphygmomanometer, and the average was documented. Venous blood samples were collected after an overnight fast. Biochemical parameters including fasting plasma glucose (FPG), 2-h plasma glucose (2h-PG) during OGTT, glycated haemoglobin A1c (HbA_{1c}), glycated albumin (GA), insulin, triglycerides (TG), total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) were assayed. Insulin sensitivity was evaluated by homeostasis model assessments of insulin resistance (HOMA-IR): HOMA-IR = fasting insulin (in mU/L) ×FPG (in mmol/L)/22.5.

Statistical analyses

Continuous variables at baseline were compared between the two groups by Student's *t* test. Comparison of categorical variables between groups was performed by χ^2 tests. Differences in the parameters before and after treatment were analysed by paired *t* test. The changes (△) in variables were compared with Student's *t* test. Statistical analyses were performed using SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA). A *P* value of < 0.05 (two-tailed) was considered statistically significant.