Precision Diets for Diabetes Prevention

NCT03919877

Statistical Analysis Plan

March 11, 2026

We hypothesized that individuals with different clinical measurements have significantly different Postprandial glycemic response (PPGRs). As the focus, participants were classified into insulin-resistant and -sensitive groups by Steady State Plasma Glucose from the insulin suppression test. The delta glucose peak was defined as the difference between the peak and the baseline. The main approach was the Mann-Whitney test (two-sided). Significant results was validated by linear regression with covariates including BMI and age. The power analysis was based on the published result in the Zeevi 2015 paper, where PPGR to bread is 44 ± 31 mg/dL*h (mean ± SD) by AUC in a population without type 2 diabetes, the required sample size is 11 (alpha=0.05 and Power=80%) in each group for Mann-Whitney test (two-sided) for detecting a group difference of 40 mg/dL*h.

Multiple machine learning models (e.g., support vector machine, regularized logistic regression, and random forest) were built to classify the metabolic subtypes, such as insulin-resistant vs insulin-sensitive groups and beta-cell normal vs beta-cell dysfunctional groups, based on CGM-measured response to a glucose drink and basic demographic and lab measurements. Model performances (auROC) were compared between models of different machine learning methods and feature sets.