שם: מיכל רייו

שם העבודה:

Personalized Nutrition by Prediction of Glycemic Responses in women with Gestational Diabetes Mellitus

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Abstract

Background:

Diabetes is a metabolic chronic disease, characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. In this study we will focus on type II diabetes (TIIDM) and Gestational diabetes mellitus (GDM). Both types present hyperglycemia or raised blood sugar which is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems. Moreover, GDM is associated with adverse pregnancy outcome for both mother and fetus.

The cornerstone of treating a diabetes is diet, and thus, it is imperative to make food choices that induce normal postprandial glycemic response (PPGRs). However, no reliable method exists for predicting PPGRs in this patient population. The common practices of using meal carbohydrate content or glycemic indices are, in fact, poor predictors for PPGRs.

Aims:

(1) To examine the associations between lifestyle parameters, anthropometrics and gut microbiome and glucose parameters of women with GDM, women with pre-diabetes and healthy women. Then, (2) To create a personalized-nutrition glycemic-control prediction algorithm in women with GDM in order to tailor a personalized nutritional treatment which will yield the best glycemic control and pregnancy outcomes. In addition, (3) to test whether the effect of diet on glycemic control is mediated by the microbiome. Moreover, (4) we would evaluate the effect of the baseline parameters and the personally dietary interventions on postpartum glycemic control and microbiome composition.

Methods:

This study is both cross-sectional and a single-blind, randomized clinical trial (RCT). The study population will consist 3 cohorts. First two were already recruited, including 275 women diagnosed with pre-diabetes and 596 healthy women, the third cohort consist 30 pregnant women diagnosed with GDM. In the RCT, only pregnant women will be part of the population. Patients will be recruited by a convenience sampling at the TLV medical center or Kaplan Medical Center. In addition, participants would be able to register online. At enrollment, a comprehensive profile will be collected from all participants including anthropometric measures, blood tests, continues glucose monitor

(CGM) for at least 1 week and a stool sample. Next, the RCT population, will be randomly assigned to one of two different nutritional recommendations arms. In the first one, "control arm", the participants will continue diet therapy as prescribed by the dietitian and follow routine perinatal care. In the second arm, "intervention arm", we will apply the pre-designed algorithm to design a diet composed of the meals predicted to have low PPGRs. The primary outcome is glycemic control and the secondary outcomes are maternal and pregnancy outcomes, including maternal stool microbiome, cesarean delivery rate and neonatal complications. For the evaluation of the primary outcome, we will measure average fasting plasma glucose, 2-hour plasma glucose and following 24-hour CGM measurement. we will be able to deeply understand their glucose balance by calculating the meal's PPGR (iAUC-incremental area under the glucose curve). In addition, we will perform follow up meetings at 3 months postpartum including CGM connection, stool sample from both mother and 75 gr of oral glucose tolerance test (OGTT).

Expected significance:

This study may reveal new associations of metabolic and microbiome parameters of women with GDM and the elevated risk of developing pre-diabetes later in life. In addition, this novel study will help to predict the best personalized diet for pregnant women with different characteristics and has the potential to significantly improve the clinical treatment provided for women with GDM.