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A Pilot Study to Assess the Feasibility, Safety and Acceptability of Soy-based Diet for Pregnant Women at High Risk for Gestational Diabetes Mellitus

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Background: Diet plays an important role in the prevention and management of gestational diabetes mellitus (GDM). Previous studies suggest that soy protein and isoflavones may have beneficial effects on lipid and glucose metabolism. Little is known regarding the cardiometabolic effects of soy intake during pregnancy. This pilot study assessed the feasibility, safety and acceptability of daily consumption of soy foods during pregnancy in women at high risk for GDM, and participant adherence to their assigned treatment.

Methods: A randomized controlled trial (RCT) was conducted among pregnant women at high risk for GDM. The Soy group were counseled to consume a combination of foods designed to contain ~25 grams of soy protein and 60-75 mg of isoflavones daily from 14 weeks until birth. They were provided with recipes and contents of different soy foods. The Control group maintained their regular diet while minimizing intake of soy containing foods. Assessments, conducted at 14 and 28 weeks of pregnancy, and 6 week postpartum, included physical measurement, questionnaire, and fasting blood samples for lipid, glucose and isoflavone metabolism biomarkers. Monthly follow-up calls were conducted to assess safety and encourage adherence.

Results: Twenty-nine subjects were recruited over a 10 month period. Both Soy and Control groups demonstrated high adherence (80-90%), defined as ≥ 15 days consuming soy foods in the past four weeks for soy group and ≤ 5 days for controls. Only five adverse events were reported possibly associated with soy intake, including nausea, vomiting, diarrhea, and itchy mouth. They were all transient and resolved without sequelae.

Conclusion: Although adherence can be challenging in such a trial, this study used a variety of approaches such as recommended recipes, dietician consultation, and monthly follow-up calls to enhance feasibility and compliance. Results indicated feasibility and adherence to treatment assignment, including the soy-based diet intervention.

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