Study Protocol with Statistical Analysis Plan and Informed Consent Form

Official Study Title: Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria

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Institution: Obstetrics Clinic – Hospital das Clínicas, University of São Paulo Medical School (HC-FMUSP), São Paulo, Brazil

Principal Investigator: Tatiana Assunção Zaccara, MD, PhD

1. Background and Rationale

Gestational diabetes mellitus (GDM) is a common complication of pregnancy and is associated with increased risk of developing prediabetes and type 2 diabetes after delivery. Clinical guidelines recommend that women with prior GDM undergo a 75-g oral glucose tolerance test (OGTT) between 6 and 12 weeks postpartum to reclassify glycemic status. However, adherence to postpartum screening is frequently low. Reminder systems have shown potential to improve attendance. Additionally, emerging evidence suggests that the 1-hour glucose measurement during OGTT may be a more sensitive marker of dysglycemia than the traditional 2-hour value. This study evaluates strategies to improve postpartum screening and compares two diagnostic approaches.

2. Objectives

Primary Objective:

Evaluate strategies to improve postpartum screening for dysglycemia among women with prior gestational diabetes.

Secondary Objectives:

1. Assess the impact of WhatsApp reminder messages on attendance to the postpartum OGTT.
2. Compare the prevalence of prediabetes and diabetes using two diagnostic strategies applied to the same OGTT.
3. Identify risk factors associated with postpartum dysglycemia.

3. Study Design

The study includes two complementary analyses conducted at the Obstetrics Clinic of HC-FMUSP.

Analysis 1 – Randomized Clinical Trial

Participants will be randomly allocated to a control group receiving standard care or an intervention group receiving WhatsApp reminders 7 and 3 days before the scheduled OGTT. If the participant does not attend, a follow-up message offering rescheduling will be sent.

Analysis 2 – Observational Diagnostic Comparison

Participants will undergo a 75-g OGTT with glucose measurements at fasting, 1 hour, and 2 hours. Two diagnostic strategies will be applied: Strategy A (fasting and 2-hour glucose) and Strategy B (fasting and 1-hour glucose). Diagnostic disagreement will be evaluated.

4. Eligibility Criteria

Inclusion Criteria:

- Diagnosis of gestational diabetes according to IADPSG criteria
- Delivery at HC-FMUSP
- Scheduled OGTT between 6 and 12 weeks postpartum
- Written informed consent

Exclusion Criteria:

- Withdrawal of consent
- Incomplete OGTT due to vomiting (excluded from analysis 2 only)

5. Outcomes

The primary outcome is attendance to the postpartum OGTT. Secondary outcomes include prevalence of prediabetes and diabetes according to each diagnostic strategy and diagnostic discordance between criteria.

6. Statistical Analysis Plan

Data will be analyzed using SPSS and R software. Continuous variables will be described using means and standard deviations or medians and interquartile ranges. Categorical variables will be presented as frequencies and percentages.

Comparisons between groups will use Student's t-test or Mann-Whitney tests for continuous variables and Chi-square or Fisher's exact tests for categorical variables. Diagnostic discordance between strategies will be assessed using the McNemar test. Statistical significance will be defined as $p < 0.05$.

7. Ethical Considerations

The study follows the principles of the Declaration of Helsinki and Brazilian National Health Council Resolution 466/2012. Participation is voluntary and participants may withdraw at any time without affecting their medical care. The study protocol was approved by the institutional Research Ethics Committee.

8. Informed Consent Form (English Version)

You are invited to participate voluntarily in the research project "Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria." The purpose of this study is to evaluate whether reminder messages improve attendance to the postpartum oral glucose tolerance test and to compare two diagnostic strategies for detecting metabolic abnormalities.

If you agree to participate, you may receive reminder messages via WhatsApp before your scheduled test. Regardless of group allocation, all participants will undergo the standard 75-g oral glucose tolerance test between 6 and 12 weeks after delivery, with blood samples collected at fasting, 1 hour, and 2 hours.

The study involves minimal risk. The only additional procedure compared to routine care is an extra blood sample collected 1 hour after glucose ingestion. All personal information will remain confidential. Your participation is voluntary and you may withdraw at any time without affecting your medical care.

If you have questions about the study, you may contact the principal investigator: Dr. Tatiana Assunção Zaccara, Obstetrics Clinic – HC-FMUSP, São Paulo, Brazil.

Participant Name: _____

Signature: _____

Date: ____ / ____ / _____