ClinicalTrials.gov Study Protocol

Official Title: Diastolic Dysfunction in the Pregnant Woman with Preeclampsia: A Prospective Observational Study at the Maternity and Neonatology Center of Tunis

Short Title: Diastolic Dysfunction in Preeclampsia

NCT Number: [to be assigned]

Date: August 2025

Sponsor/Responsible Party: Maternity and Neonatology Center of Tunis

Principal Investigator: [DR Sarra zarrouk, MD, Maternity and Neonatology Center of Tunis, Tunisia, zarrouk.sarah958@gmail.com]

1. Objective

The objective of this study is to evaluate diastolic function in pregnant women with preeclampsia and to compare findings with normotensive pregnant women.

2. Study Design

- Study Type: Observational (Case-Control)
- Study Model: Case-Control, two cohorts (Preeclampsia vs. Normotensive)
- Time Perspective: Prospective
- Enrollment: 80 participants (40 in each cohort)
- Follow-up Duration: Until delivery and immediate postpartum (up to 7 days)

3. Study Setting and Duration

This study was conducted within the Anesthesia-Resuscitation and Gynecology-Obstetrics Departments (A, B, C, and D) of the Maternity and Neonatology Center in Tunis, Tunisia, over a 5-month period from March 2025 to June 2025.

4. Eligibility Criteria

Inclusion Criteria:

- Pregnant women aged 18–45 years
- Third trimester of pregnancy
- Group A: women diagnosed with preeclampsia (≥140/90 mmHg after 20 weeks + proteinuria ≥300 mg/24h, with or without severity criteria)
- Group B: normotensive pregnant women without proteinuria (<300 mg/24h if tested)

Exclusion Criteria:

- Pre-existing cardiovascular disease (valvulopathy, cardiomyopathy, EF <50%)
- Congenital heart disease, arrhythmia, prior cardiac surgery
- Chronic hypertension (before 20 weeks)
- Pulmonary hypertension (pre- or post-capillary)
- Systemic disease with cardiac involvement (SLE, Behçet's disease)
- Technical difficulty preventing echocardiographic evaluation
- Unusable medical records or diagnostic uncertainty
- Gestational hypertension without preeclampsia

5. Study Procedures

Data Collection:

- Demographics, medical history, clinical and biological data collected using standardized forms.
- Echocardiographic parameters recorded according to ASE/EACVI 2016 guidelines.

Echocardiographic Parameters Assessed:
- Transmitral Doppler flow (E wave, A wave, E/A ratio, Deceleration Time)
- Tissue Doppler imaging (E′ septal, E′ lateral, A′, S′)
- Indexed left atrial volume
- Maximum tricuspid regurgitation velocity (Vmax TR)

Classification of Diastolic Function:
- Normal
- Indeterminate
- Diastolic Dysfunction (Grade I = impaired relaxation; Grade II = pseudonormal; Grade III = restrictive)

6. Outcome Measures

Primary Outcome:
- Title: Prevalence of left ventricular diastolic dysfunction in preeclamptic women
- Description: Echocardiographic evaluation based on ASE/EACVI 2016 criteria
- Time Frame: At echocardiographic evaluation during the third trimester

Secondary Outcomes:
1. Comparison of diastolic parameters between preeclamptic and normotensive groups (E′, E/E′, LA volume, TR velocity).
2. Association between diastolic dysfunction and maternal symptoms (dyspnea, palpitations, pulmonary edema).
3. Correlation between severity of preeclampsia and degree of diastolic dysfunction.
- Time Frame: During pregnancy and up to 7 days postpartum.

7. Statistical Analysis Plan

- Continuous variables expressed as mean ± SD; compared using Student's t-test or Mann-Whitney U test.
- Categorical variables expressed as counts (%) and compared using Chi-square or Fisher's exact test.
- $p < 0.05$ considered statistically significant.
- Subgroup analysis: association between severity of preeclampsia and prevalence of diastolic dysfunction.

8. Ethical Considerations

- Study approved by the Local Ethics Committee of the Maternity and Neonatology Center of Tunis.

- Written informed consent obtained from all participants.
- Confidentiality, anonymity, and protection of personal data ensured.

9. References

ASE/EACVI 2016 Guidelines on Diastolic Function.
Melchiorre K et al. Circulation. 2011.
Guirguis G et al. J Am Soc Echocardiogr. 2015.