Neuropathic Pain in Pregnancy

Protocol # 204737

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Statistical Methods and Data Management

All data will be kept either in locked file cabinets or password-protected computers accessible to only investigators or designated study staff. Trained study staff will enter data and original source documents will be stored in locked file cabinets in offices with limited access. A database will also be created to input subject information and only designated study staff will have access. Periodic reviews will occur to ensure that data is accurately entered and if needed, corrections can be made. The database will generate queries to account for missing information. Every subject enrolled in this study will be given a unique ID number that will be used for tracking purposes. The key linking the unique study ID number to identifiable information will also be stored in the password-protected computers accessible to only investigators or designated study staff.

Each subject's name, SSN, birth date, address, phone number, and email address will be obtained for purposes of payment and follow-up. We will ask for each subject's drug use history, medical history, and current drug use.

Part A:
Descriptive statistics will be calculated for all measures obtained.

For the first hypothesis, primary outcome measures include VAS and pain assessments. Secondary outcome measures include BDI, PGIC, and CGI-I. For each outcome measure, scatter plots will be constructed for visual inspection across time by group. As outcome measures will be obtained at multiple time points, mixed models will be used to account for the correlations among the measurements within the subjects.

Table 3 provides a list of specific outcome data of interest for the second hypothesis. The occurrence of obstetrical outcomes will be compared between the three groups. If measures are normally distributed, we will use ANOVA to test the differences among the three groups. Otherwise, we will use a non-parametric method, such as Kruskal Wallis test, to test the difference among the groups.

Table 3: Specific Outcome Data

Obstetrical Records	Neonatal Records
• Preterm labor • Preterm birth • Premature rupture of membranes • Mode of delivery	• 1 minute and 5 minute APGAR Scores • Length of Hospitalization • Neonatal Intensive Care Unit Admission • Neonatal Abstinence Syndrome • Birth weight and length • Gender

Part B (rTMS):
We will determine the acceptability of rTMS as a treatment option by determining the percentage of subjects who accept the treatment when offered. Tolerability will be determined by the reporting of adverse events. The primary outcome measure is VAS. Secondary outcome measures include BDI, PGIC, and CGI-I. For each outcome measure, scatter plots will be constructed for visual inspection across treatment. Using previous studies of rTMS for the treatment of neuropathic pain, we will determine an effect size and complete a power analysis. This information will help guide future studies of the effectiveness of rTMS in the treatment of neuropathic pain in pregnancy.

Neonatal outcomes will be analyzed between the following groups: 1. Subjects participating in rTMS (Part B); 2. Subjects with neuropathic pain who participated in Part A but did not participate in Part B; 3. Subjects with chronic non-neuropathic pain who participated in Part A; and 4. Subjects without chronic pain who participated in Part A. Specific endpoints of interest include neonatal intensive care unit admission, length of hospitalization, birth weight and length, and 1-min and 5-min APGAR scores. The occurrence of obstetrical outcomes will be compared between the groups. If measures are normally distributed, we will use ANOVA to test the differences among the three groups. Otherwise, we will use a non-parametric method, such as Kruskal Wallis test, to test the difference among the groups.

Neonatal outcomes will be scrutinized after each delivery and neonatal period. The investigator team will convene and review all neonatal outcomes to determine if any complication occurred that could be attributed to the study, participation in the study, and/or treatment received. If any complication is identified (i.e. preterm delivery with all subjects who participated in rTMS), we will cease all current and potential study procedures related to part B of the study.

All statistical analysis will be completed using SAS 9.4. Significance will be set at $p<0.05$.