TENS and Opioid Use After Cesarean Delivery

NCT03843788

Document Type: Study Protocol

Document Date: 7/19/2022

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THE STATE UNIVERSITY OF NEW JERSEY

INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

(HRP-503a)

STUDY INFORMATION

Title of Project: Transcutaneous Electrical Nerve Stimulation (TENS) and Maternal Opioid Use after Cesarean Delivery

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PROTOCOL VERSION AND DATE: Version 5, July 2, 2019

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1.0 Research Introduction

1.1 Purpose/Specific Aims

To explore the effects of Transcutaneous Electrical Nerve Stimulation (TENS) therapy in the pain management of postpartum women.

A. Objectives

- To determine if the addition of TENS therapy to the pain management of women post-C-Section leads to less opioid medication use.
- To evaluate the efficacy of TENS therapy as a means of alternative pain relief for women post-C-section (CS) and for postpartum women with a history of opioid use.

B. Hypotheses / Research Question(s)

We hypothesize that patients that receive TENS therapy will report lower pain scores and request less opioid medication than the control group. We anticipate improved control in particular in the group of women with a history of opioid use.
Additionally, we believe that the TENS therapy will show benefits in other postpartum outcomes including time to bowel movement, level of sedation, and time to out of bed.
Overall, we anticipate that this pilot study will support the application of TENS therapy in postpartum pain management.

1.2 Research Significance *(Briefly describe the following in 500 words or less):*

This pilot project will evaluate the effects of Transcutaneous Electrical Nerve Stimulation (TENS) on intensity of incisional symptoms, pain medication usage and patient satisfaction with pain control in women after Cesarean Section (CS).

Over 1 million women in the United States deliver via Cesarean Section (CS) annually. Women are prescribed opioid medications for pain management both during the inpatient stay and upon discharge home following Cesarean Section delivery in the United States (Osmundson et al, 2017; Bateman et al, 2017; Fahey, 2017). Health care providers must balance the risks and benefits of providing opioid pain medications to women after childbirth (Dowell et al, 2016). Alternative pain relief therapies delivered to women in acute post-operative pain after CS during the inpatient hospital stay are critically needed to reduce the quantity of opioids provided to new mothers after birth.

The use of opioid medications for new mothers presents notable risk of adverse events for both mother and baby. Following an incident in which a newborn died from morphine poisoning when his mother was prescribed codeine while breastfeeding, additional research efforts have illuminated the hazards of opioid use in new mothers. Breastfeeding mothers who are rapid metabolizers of CYP450 produce much more morphine from ingested codeine. (FDA.gov) Therefore, there is a risk of infant toxicity when breastfeeding mothers are taking certain opioids. Willman et al (2009) found that "opioids can accumulate in babies despite only small quantities of maternal opioids excreted in breast milk because neonates and babies less than 6 months have as much as a fourfold reduced ability to clear the small quantities of opioids consumed compared to babies older than 6 months." Elevated levels in newborns can lead to analgesia, sedation, and life-threatening respiratory depression.

In addition to toxicity, prescribing opioids to new mothers, whether breastfeeding or not, bears a risk of misuse and addiction. The Substance Abuse and Mental Health Services Administration reports an annual average of approximately 21,000 pregnant women who have misused opioids in the past month. Access and adherence to opioid use disorder treatment remains a significant hurdle for new mothers. The accumulation of these risks underscore the clinical significance of finding alternative pain relief methods.
Non-pharmacological interventions for pain management, such as Transcutaneous Electrical Nerve Stimulation (TENS), have been shown to reduce painful incisional symptoms and reduce intake of opioid pain medications in women after CS (Jaafarpour et al, 2008; Kerai et al, 2011; Karakaya et al, 2011). TENS is a low-cost, effective intervention that can be applied safely by physical therapists, nurses and physicians on the inpatient floor. Studies have demonstrated that patients can be educated on self-administration of TENS. This pilot project proposes the use of TENS on the inpatient postpartum floor starting at 8 hours post-operatively and continuing until discharge home. It is hypothesized that women who utilize TENS after CS will consume less opioid medication during the inpatient stay compared to women who do not utilize TENS after CS.

1.3 Research Design and Methods

OVERVIEW. This study is a pilot randomized interventional trial. Two categories of participants will be randomly assigned to an invention or control group, using a random number generator: normal cesarean without associated comorbidity, or cesarean in women with a history of opioid addiction, as defined by use of opioid replacement medications of either methadone or Subutex during pregnancy. The control group will receive usual care which is

standard post-operative pain management with opioids and NSAIDS. The intervention group will receive usual care plus TENS therapy beginning 8 hours after C-section and continuing to discharge. Both groups will receive medications for pain as requested or ordered by the doctor.

RESEARCH PROCEDURES. Patients will be identified for participation in several locations. Prenatal patients at the Rutgers Medical Group Obstetrics and Gynecology or Maternal Fetal Medicine practices, or the High Risk Obstetric Perinatal Clinic will be approached for study inclusion. Physicians that have a direct treatment relationship with the patient will inform the patient about the study and invite them to enroll. Consent for participation will be reviewed with the principal investigator and signed prior to delivery hospitalization. Randomization will follow consent, and patients randomized to intervention will have teaching performed about how to use the device at the time of consent.

Following cesarean delivery, subjects will be re-approached in the Postpartum Unit at Robert Wood Johnson University Hospital by study staff. The TENS device will be again reviewed, and provided to the patient, with review of instructions for use. The patients in the intervention group will be educated on the proper way to utilize the TENS unit. They will apply the patches of the TENS unit above and below the C-section site. Specifically, the electrode patches will be placed above the abdominal bandages post-operatively and replaced above the abdominal bandages after the dressing change on post-operative day 1. Starting 8 hours after C-Section, the TENS unit will be turned on to a comfortable intensity as determined by the patient and will remain on until the patient is discharged, to be removed for toileting and showering and at the patient's discretion. Once the TENS unit is applied and turned on, the patient will not have to do anything else to maintain the therapy. Study staff will provide a record for documentation of time on/off for the unit. Additionally, a member of the study staff will check on the device daily to ensure proper maintenance. On the day of discharge, study staff will collect the device, and conduct a short survey about pain scores. They will then review pain scores, pain medication usage and other secondary outcomes in the patient's chart. Finally, pain will be reassessed at the subject's outpatient postpartum visits by study staff. The subjects will complete a measure of perceived physical disability at the outpatient postpartum visit.

DATA COLLECTION. Our research team members will collect the following data points from the patient's inpatient medical record: pain scale scores, medication requests/prescriptions (including name, type, and amount), time to first bowel movement, subjective incision site complaints, and time to OOB. Participants will complete a survey before discharge which will solicit additional information about the postpartum recovery experience with or without TENS therapy. (Survey is submitted with this protocol as Appendix A.) Participants will complete a survey at the 6-week postpartum visit on perceived difficulties because of health (The survey, WHODAS 2.0, is submitted with the protocol as Appendix B).

DURATION OF STUDY. Study duration will be no more than 12 weeks. This will include up to 6 weeks prior to delivery for study approach and consent, delivery hospitalization, and 6 weeks postpartum for pain assessments at postpartum visits. There will be no long-term follow up.

PRIMARY and SECONDARY ENDPOINTS. Primary endpoint of this pilot study is a total of 10 normal patients undergoing cesarean, and 10 patients with history of opioid addiction. Intervention will be performed in 5 patients in each group. Safety data will be reviewed following the first 10 patients to evaluate for worsening patient scores relative to controls.

1.4 Preliminary Data

Preliminary data in 10 studies supports the use of high frequency TENS (>100 Hz) for pain relief post-Cesarean. Alves Lima et al (2014) compared the effectiveness of high frequency (100 Hz) and low frequency (4 Hz) TENS for pain relief post-Cesarean. High frequency TENS was more effective to reduce pain than low frequency TENS ($p<0.05$). A review by Vance et al (2014) confirmed the superior effectiveness of high frequency TENS compared to low frequency TENS for acute post-surgical pain and for patients taking opioid medications. Since women after Cesarean Section in this study will have acute post-surgical pain and be prescribed opioid medications, high frequency TENS was selected for the study intervention.

Literature support exists for both continuous and 30-minute interval settings for the delivery of TENS after Cesarean Section for 24, 48 and 72 hours post-operatively. Six out of the 10 preliminary studies utilized continuous TENS rather than 30-minute intervals in order to increase the total dosage of electrical stimulation intervention delivered to patients after surgery over the inpatient hospital stay. While both continuous and interval settings of TENS have been shown to be therapeutically effective to reduce pain, differences in subjects' perception of comfort with TENS may exist between continuous and interval settings, with continuous being rated as more comfortable. This protocol has selected continuous TENS because: 1) continuous TENS has been shown to be as effective as 30-minute TENS intervals, and 2) continuous TENS may allow participants to receive a lower intensity electrical stimulation over a longer duration, thereby providing a comparable dosage of electrical stimulation over time when compared to a higher intensity over a shorter period of time (30-minutes). This distinction is important because women in this study will be experiencing acute post-surgical pain after Cesarean Section delivery. The research team has selected continuous TENS setting at a subject-selected intensity that is comfortable in order to afford participants the same therapeutic benefit as 30-minute interval TENS, which would be set at a higher sensory threshold intensity and which may not be as comfortable for participants in order to be therapeutically effective.

Souza Alves 2015 published results of a clinical randomized study in which 30 women received TENS for 30 minutes post-CS and 30 post-CS women in a control group did not. For the intervention group, there was a statistically significant decrease in the reported pain intensity before and after electrical stimulation ($p=0.001$). (Figure 1) There was not a significant difference between the pain intensity between control and intervention.

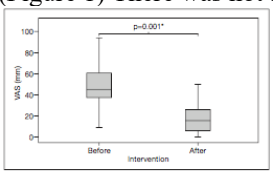


Figure 1. Medians and their quartiles before and after intervention
VAS = visual analog scale; intervention group = Before (Md=45.00; 1st quartile=36.00 and 3rd quartile=60.00); After (Md=15.50; 1st quartile= 5.75 and 3rd quartile=27.50); Wilcoxon test; *Statistical significance (p≤0.05).

Karakaya et al (2012) published results of a clinical randomized study in which women received TENS for 30-minute intervals, combined with physiotherapy in the postpartum room (n=26), or usual postpartum care (n=24). There was a statistically significant difference between the intervention group and the control group in pain intensity at both POD-1 and POD-2.

Table 1

	Intervention Group	Control Group	t	p value
POD-0	0.612 +/- 0.268	0.668 +/- 0.315	-0.689	0.494
POD-1	0.362 +/- 0.173	0.532 +/- 0.280	-2.612	0.012
POD-2	0.352 +/- 0.194	0.514 +/- 0.280	-2.391	0.021

There are many research publications that suggest that TENS is an effective pain relief method post-Cesarean section. However, there has not been any published data examining whether TENS throughout delivery hospitalization when opioid use is the highest can provide an alternative to prescribing opioids to post-CS patients.

1.5 Sample Size Justification

This is a pilot feasibility study to evaluate effectiveness and acceptability in our patient population of TENS use throughout delivery hospitalization. We aim to have 20 participants total: 5 in control and 5 in intervention without history of opioid addiction, and 5 in control and 5 in intervention with history of opioid addiction/misuse. This sample size is comparable to other shorter term pilot studies. This pilot study will serve as the basis for larger trials in the future, with larger sample size powered to demonstrate reduction in pain scores. We anticipate recruitment for this trial will take approximately 6-9 months.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The intervention for this study will be the application and use of Transcutaneous Electrical Nerve Stimulation (TENS) unit. The TENS unit uses low-voltage electric currents to temporarily block pain receptors and is currently used to treat bone, muscle, and joint pain. The TENS unit is not part of standard inpatient postpartum care.

B. Dependent Variables or Outcome Measures

Dependent variables will include: pain ratings and subjective incisional complaints, number and type of pain medications used, patient satisfaction with pain control, time to first bowel movement, level of sedation and time to OOB. Secondary measures will include pain surveys at discharge, and at 6 weeks postoperatively.

1.7 Drugs/Devices/Biologics

Device: FDA–approved TENS unit.

The TENS unit has four small adhesive patches which will placed above and below the surgical incision site. The device will be set to a frequency between 100 and 120 Hz and utilize low-volt, pulsed current.

A. Drug/Device Accountability and Storage Methods

- *Indicate the specific location where study drugs/devices/biologicals will be stored and secured.*
  The device will be stored in a locked cabinet in Dr. Duzyj's locked office.
  125 Paterson St, Rm 2124
  New Brunswick, NJ 08901

- *Indicate who will be responsible for preparation, dispensing and disposal of study drug/device/biological.*
  The TENS device will be obtained and checked by Adrienne Simonds. It will be reevaluated with quality checks after each patient usage. New TENS pads will be provided for each patient. Dr. Duzyj will clean and sterilize the pads before application and as needed.

1.8 Primary Specimen Collection

N/A

1.9 Interviews, Focus Groups, or Surveys

A. Administration

Postoperative pain evaluation will be conducted using the survey tool, included as Appendix A. This will be provided by study staff

- **Timing and Frequency**

Survey will be performed at hospital discharge, as well as at 6 weeks postpartum.

- **Location**

Surveys will supplied to patient at bedside at discharge, and in the outpatient office during routine postpartum visit. However, if patients do not present for their routine 6 week postpartum visit, the final survey will be mailed to their last address of record, with a self-addressed stamped envelope to facilitate completion of study activities.

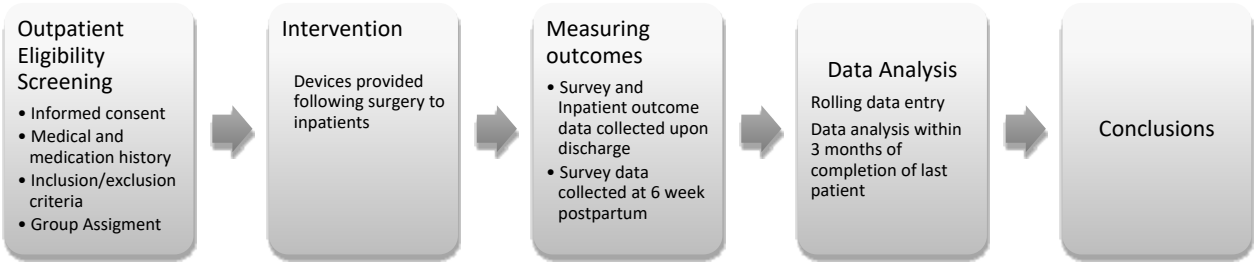
- **Procedures for Audio and Visual Recording**

N/A

B. Study Instruments

- Variables of interest for our study include perceptions of intensity and quality of postoperative pain. Two validated questionnaires will be used to achieve this objective as bulleted below. Additionally, basic questions about the acceptability of the TENS device in the post-cesarean setting, and intended vs. actual use are valuable for us to determine whether TENS is an acceptable modality for most women.
- The research questionnaire (Appendix A and B) will include 4 components:
  1. The McGill Pain Questionnaire, developed by Dr. Melzack at McGill University
  2. The Neuropathic Pain Scale, developed by Drs. Galer and Jensen
  3. General questions about acceptability of the TENS unit in the postoperative setting.
  4. The WHO-DAS 2.0, developed by the World Health Organization, at the 6 week postpartum visit only (Appendix B).

1.10 Timetable/Schedule of Events



2.0 Project Management

2.1 Research Staff and Qualifications

Dr. Simonds is an Assistant Professor in Physical Therapy with expertise in post-Cesarean pain management. She has expertise in TENS usage and will provide technical support and oversight for the trial.

Dr. Duzyj Buniak is a Maternal Fetal Medicine attending. She conducts translational research in cesarean scar healing and has an interest in cesarean healing. She provides prenatal care for patients in both the MFM practice, and in the High Risk OB perinatal clinic, where she is medical director. As such, she will be able to facilitate study enrollment and consent. She conducts multiple clinical studies, and has expertise to facilitate study procedures, and data analysis.

Imani Sanders is a medical student who will help facilitate study activities, including survey conduct, TENS instructions and data collection. Dr. Hill is a fellow in Maternal Fetal Medicine. Similar to Imani Sanders, she will facilitate study activities including survey conduct, TENS instructions and data collection. Brooke Baker is a physical therapy student who will help facilitate study activities, including data entry and analysis, and write up.

Shama Khan is the study coordinator who will help with the regulatory aspects of study oversight and approval.

J. Scott Parrott, PhD is a biostatistician who will assist in interim and final data analysis.

2.2 Resources Available

Facilities-The postpartum maternity unit at Robert Wood Johnson Medical School provides high level care for women after Cesarean delivery.

Medical Or Psychological Resources- Dr. Duzyj will be available to provide medical oversight and answer patient questions during treatment.

Research Staff Training- Dr. Simonds will be responsible for oversight and training of the team related to use of the TENS unit.

2.3 Research Sites

Robert Wood Johnson University Hospital – Postpartum Unit and High Risk Obstetric Clinic
1 Robert Wood Johnson Place
New Brunswick, NJ 08901

Robert Wood Johnson Medical Group
125 Paterson St, Suite 4100
New Brunswick, NJ 08901

3.0 Multi-Site Research Communication & Coordination

N/A

4.0 Research Data Source/s

4.1 Primary Data-Subjects and Specimens

Female patients planning for cesarean delivery at Robert Wood Johnson University Hospital

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details

Recruitment will start in July 2018 (pending IRB approval). Patients will be identified for participation in several locations. Prenatal patients at the Rutgers Medical Group Obstetrics and Gynecology or Maternal Fetal Medicine practices, or the High Risk Obstetric Perinatal Clinic will be approached for study inclusion. Physicians that have a direct treatment relationship with the patient will inform the patient about the study and invite them to enroll. The recruitment method will be a direct discussion of the study through face-to-face interactions with patients during standard prenatal care. The informing statement will closely resemble: *"We are conducting a study to see if patients recovering from a C-section will find pain relief from using a small portable machine called a TENS unit. The TENS unit is currently used as a safe method for muscle pain relief and may reduce the need for opioid medication. Would you like to participate?"* To attenuate concerns of authoritative pressure, the physician will assure the patient that their decision to participate or not participate will not impact the quality of care they receive. Consent for participation will be reviewed with the principal investigator and signed prior to delivery hospitalization. Randomization will follow consent, and patients randomized to intervention will have teaching performed about how to use the device at the time of consent.

B. Source of Subjects

Patients will be identified for participation in several locations. Prenatal patients at the Rutgers Medical Group Obstetrics and Gynecology or Maternal Fetal Medicine practices, or the High Risk Obstetric Perinatal Clinic will be approached for study inclusion.

C. Method to Identify Potential Subjects

Dr. Duzyj Buniak will inform physicians and staff in the practices mentioned of the planned study. She will be contacted regarding potential patients, and be available for a prenatal visit for interested subjects.

D. Subject Screening

- Physicians that have a direct treatment relationship with the patient will inform the patient about the study and invite them to enroll. Dr. Duzyj will confirm eligibility thereafter.

- **Inclusion Criteria**

- Women aged between 18 and 45 years
- Understand and be able to follow written and oral instructions in English
- Provide written informed consent
- History of prior opioid addiction for half of the patients. (Opioid use will be obstetric patients on narcotic replacement with methadone or subutex.)

- **Exclusion Criteria**

History of cardiac arrhythmia or pacemaker usage

E. Recruitment Materials
N/A
F. Lead Site Recruitment Methods
N/A

4.3 Subject Randomization
A random number generator will be used for randomization, with even groups randomized to no intervention, and odd groups to intervention.

4.4 Secondary Subjects
N/A

4.5 Number of Subjects

A. Total Number of Subjects
20
B. Total Number of Subjects If Multicenter Study
N/A
C. Require Number of Subjects to Complete Research
40
D. Feasibility of Recruiting
We anticipate approximately half of the patients approached will consent to this trial.

4.6 Consent Procedures

A. Consent

- **Documenting Consent**

Adult consent form provided.

- **Waiver of Documentation Of Consent**

N/A

- **Waiver or Alteration of Consent Process**

(i) Waiver or Alteration Details
N/A
(ii) Destruction of Identifiers
N/A
(iii) Use of Deception/Concealment
N/A

B. Consent Process

- **Location of Consent Process**

Prenatal patients at the Rutgers Medical Group Obstetrics and Gynecology or Maternal Fetal Medicine practices, or the High Risk Obstetric Perinatal Clinic will be approached for study inclusion. Consent will occur in these locations.

- **Ongoing Consent**

Consent will be reconfirmed following delivery prior to application of the device.

- **Individual Roles for Researchers Involved in Consent**

Dr. Duzyj or Dr. Hill will obtain informed consent. Imani Sanders, Dr. Hill or Dr. Duzyj will reconfirm consent at the time of device application.

1. Consent Discussion Duration

20-30 minutes

2. Coercion or Undue Influence

The patient will be reassured that non-inclusion in the study will result in routine standard of care

3. Subject Understanding

The device will be available at the time of consent to trial prior to cesarean, in order to ensure patients have good expectations of their postpartum course.

4.7 Special Consent/Populations

A. Minors-Subjects Who Are Not yet Adults

- **Criteria for Consent of Minors**

Patients under the age of 18 will not be permitted to participate in this study. We will verify with inpatient medical records to confirm that participant is over the age of 18.

- **Wards of the State**

1. Research in NJ Involving Minors

N/A

2. Research Outside of NJ Involving Minors

N/A

- **Parental Permission**

N/A

- **Non-Parental Permission**

N/A

- **Assent Process**

N/A

1. Documentation of Assent

N/A

- **Non-English Speaking Subjects**

None, only English-speaking subjects are eligible for this study.

1. Process for Non-English Speaking Subjects

N/A

- **Short Form Consent for Non-English Speakers**

N/A

B. Adults Unable to Consent / Cognitively Impaired Adults (*for interventional studies*)

- **NJ Law-Assessment of Regaining the Capacity To Consent**

If the attending clinician caring for the patient considers her able to consent for cesarean surgery, this will be considered sufficient for capacity to consent for this research trial.

- **Capacity To Consent**

Surrogate consent will not be sought.

- **NJ Law-Selecting A Witness**

Nursing or medical staff in the prenatal office may serve as a witness to consent if necessary.

- **Removing a Subject**

If a patient withdraws consent at the time of cesarean or at any time of device application, no outcome data will be collected, and all study documents including consent and log of TENS

device will be destroyed by shredding. If a subject requests removal after data collection, data will be destroyed.

4.8 Economic Burden and/or Compensation for Subjects

A. Expenses

None

B. Compensation/Incentives

Subjects will be provided with a $25 gift card for study participation at the conclusion of all study procedures, during the 6 week postpartum visit. If the subject fails to present for the 6 week visit, the gift card will be mailed to the subject along with the final survey, as well as a signature form confirming receipt of gift card for regulatory confirmation. This will be sent via certified mail to confirm receipt.

C. Compensation Documentation

Gift card distribution will be signed by the patient and kept in a log with the patient's consent.

4.9 Risks to Subjects

A. Description of Subject Risk

Research has shown that TENS therapy is a safe device when used appropriately after surgery. Minor tingling is normal during TENS therapy. However, some patients find the tingling sensation from the device to be uncomfortable when the intensity of the device is too high. If this occurs, the intensity may be turned down. In rare cases, patients have developed adverse skin irritation or rash at the sites where the electrodes are placed. There are no anticipated long-term complications to cesarean scar wound healing.

There is also the risk of loss of privacy. However, data will be associated with a subject study ID number, and protected health information will not be recorded.

B. Procedures for Risks to Embryo, Fetus, and/or Pregnant Subjects

None, as all interventional study procedures will be conducted postpartum.

C. Risks to Non-Subjects

None

D. Assessment of Social Behavior Considerations

Postoperative pain is a common cause of stress, especially in the postpartum period. In other pilot studies, this device has demonstrated good acceptability among patients. However, it is possible that a new mother may feel overwhelmed by the addition of a device for pain management.

- **Reasonably Foreseeable Risks**

  This risk is overall low. Device use is unlikely to increase potential for postpartum stress or mood disorders.

- **Risk Of Imposing An Intervention On Subject With Existing Condition**

  Patients with known history of cardiac arrhythmia or pacemaker will be excluded. However, the subject will be instructed to stop use of the device and call the study staff if palpitations occur.

- **Other Foreseeable Risks**

  None

- **Observation And Sensitive Information**

  Use of postoperative narcotic pain medication is highly individual in the inpatient setting, and may be considered sensitive. However, in data collection, PHI will not be associated with any documentation of study outcome measures, including drug related information.

E. Minimizing Risks

The patient will be taught about methods to reduce skin and muscle tingling at the time of device application. The lowest effective setting will be used. She will be assessed for palpitations when the device is turned on.

F. Certificate of Confidentiality

N/A

G. Potential Benefits to Subjects

Potential for decreased postoperative pain and decreased narcotic use.

H. Provisions to Protect the Privacy Interests of Subjects

No protected personal health information will be recorded. Surveys and data collected will be labeled only with subject study ID. Consent forms will be the only source of PHI, which will be kept locked in the research coordinators office.

I. Research Team Access to Subject Data

Data will be collected from the Sunrise Clinical Manager inpatient record. It will be directly imputed into an Excel spreadsheet, without use of identifiers.

4.10 Secondary Data – Records/Chart Reviews/Databases/Tissue Banks/etc.

N/A

4.11 Chart/Record Review Selection

Data will be collected by Imani Sanders. It will be collected at the time of discharge survey conduct on the RWJUH postpartum floor. Items collected from the patient's flowsheets will include pain ratings and subjective incisional complaints, number and type of pain medications used, patient satisfaction with pain control, time to first bowel movement, level of sedation and time to OOB. This will be directly imputed into an Excel spreadsheet on the investigator's password protected laptop provided by the Rutgers IT department, without identifiers.

4.12 Secondary Specimen Collection

N/A

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 NJ Access to Medical Research Act

N/A

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. "Special" Classes Of Subjects

No special classes will be included, as all interventional study procedures will be conducted postpartum.

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. Primary outcome measures of daily median pain scores will be compared using nonparametric statistical methods. Survey responses will also be compared using Chi-square for proportions, and non-parametric methods for ordinal data.

B. Power analysis is not performed as this is a pilot study.

C. No PHI will be recorded in any datasheet. Data sheets will be maintained in a password protected file on the password protected principle investigators' laptop.

D. Because all data will be collected at the time of subject discharge, data should be complete and clean for each individual at the time of collection.

E. Data will be shared through University secure email among study investigators only. Source data will be destroyed following data analysis, anticipated to be 1 year after completion of study procedures.

6.2 Data Security

No PHI will be recorded in any datasheet. Data sheets will be maintained in a password protected file on the password protected principal investigators' laptop. Laptop will be provided by the Rutgers IT department.

6.3 Data and Safety Monitoring

A. Periodic Data Evaluation

Data will be evaluated after pairs of intervention and control subjects are enrolled to compare differences. If 3 consecutive sets of intervention/controls demonstrate worse outcomes for intervention subjects, the study will be suspended. Additionally, interim data analysis will be performed by the project statistician after enrollment of 50% of subjects to ensure that device usage does not cause increased pain.

B. Type of Data Evaluated

Median daily pain score, and survey results.

C. Collection of Safety Information

Direct access into the EMR at discharge, conduct of survey with the patient.

D. Frequency of Data Collection

After each pair of intervention/control

E. Reviewer of Data

Dr. Duzyj, Dr. Simonds and the statistician Dr. Parrott

F. Schedule of Review of Cumulative Data

Every 6 months

G. Tests for Safety Data

Non-parametric analysis of median daily pain score.

H. Suspension of Research

If 3 consecutive sets of intervention/controls demonstrate worse outcomes for intervention subjects, the study will be suspended.

6.4 Reporting Results

A. Sharing of Results with Subjects

Subjects will not be re-contacted to share results.

B. Individual Results

None

C. Aggregate Results

None

D. Professional Reporting

Professional reporting will be at national conferences and journals in obstetrics and gynecology, as well as physical therapy.

E. ClinicalTrials.Gov Registration and Data Reporting

This study will be reported to ClinicalTrials.gov

6.5 Data Sharing

N/A

7.0 Data and/or Specimen Banking

N/A

8.0 Other Approvals/Authorizations

N/A

9.0 Bibliography

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