TENS and Opioid Use After Cesarean Delivery

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RUTGERS THE STATE UNIVERSITY OF NEW JERSEY
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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Transcutaneous Electrical Nerve Stimulation (TENS) and Maternal Opioid Use after Cesarean Delivery
Principal Investigator: Dr. Adrienne Simonds
Co-Investigators: Dr. Christina Duzyj Buniak

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part in it, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this informed consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. Simonds is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Duzyj Buniak is the investigator responsible for activities at Robert Wood Johnson University Hospital.

Dr. Simonds may be reached at:
856-566-7190
Rutgers School of Health Professions
200 College Drive, Jefferson Hall, Rm 224
Blackwood, NJ 08012

Dr. Duzyj Buniak may be reached at:
732-235-6632
Rutgers Robert Wood Johnson Medical School
Clinical Academic Building, Rm 2124
125 Paterson Street
New Brunswick, NJ 08901

Dr. Duzyj Buniak or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
This study seeks to evaluate the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) in decreasing use of opioid medication in new mothers.

The TENS unit is a small, portable FDA-approved device that is currently used for muscle pain relief. The device has small, adhesive patches that are placed on the part of the body where you are experiencing pain. The device produces electrical pulses that stimulate sensory nerves on the body part where you are experiencing pain. The electrical pulses help activate natural pain relief mechanisms within the body. This study will reveal whether the device can provide similar pain relief to new mothers after C-section at the incision site and reduce the need for postpartum opioid use.

Opioids are a broad group of pain-relieving drugs that work by interacting with your nervous system. Common opioids include OxyContin, Vicodin, codeine, morphine, and many others. Women are often prescribed opioid medications for pain management after giving birth by C-section. However, opioid medications are addictive, and it is sometimes difficult for health care providers to balance the risks and benefits of providing opioids. Alternative pain relief therapies for new mothers are critically needed to reduce the quantity of opioids provided to new mothers.

Who may take part in this study and who may not?
Patients giving birth at Robert Wood Johnson University Hospital (RWJUH) are invited to participate in this study.

You may not participate in this study if you are under the age of 18, or have a history of abnormal heart rhythm or a pacemaker.

Why have I been asked to take part in this study?
You are being asked to participate because you will be giving birth by C-section at RWJUH.

How long will the study take and how many subjects will take part?
The study will begin 8 hours after your C-section and last the duration of your hospital stay. Your participation in the study will end at your 6 week postpartum follow-up appointment. We aim to have 20 subjects in this study.

What will I be asked to do if I take part in this study?
If you agree to take part in a study, you will be randomly assigned to one of 2 groups, an intervention group using TENS or a usual care group (control). If you are assigned to the intervention group, you will receive TENS therapy beginning at 8 hours after your C-section and continuing throughout your hospital stay, to be removed for toileting, showering and at your discretion. *Following your C-section delivery, you will be approached in the Postpartum Unit at Robert Wood Johnson University Hospital by study staff. The TENS device will be reviewed, and provided to the you, with review of instructions for use. You will be educated on the proper way to utilize the TENS unit. Patches of the TENS unit will be applied above and below the C-section site.* The control group will receive usual care. Both groups will receive medications for pain as requested or as ordered by your doctor. You will be asked to complete a short survey on the day of your discharge and again at your 6-week postpartum visit to describe details of your experience using the TENS device while in the hospital.

What are the risks and/or discomforts I might experience if I take part in this study?

Research has shown that TENS therapy is safe when used appropriately after surgery. A tingling sensation is normal during TENS therapy. However, some patients find the tingling sensation from the device to be uncomfortable if the intensity of the device is too high. Should this occur, you should turn the intensity down to be more comfortable. In rare cases, patients have developed adverse skin irritation or rash at the sites where the electrode patches are placed. There are no anticipated long-term complications to your Cesarean scar wound healing.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may include reduced pain around C-section site if the device is used. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study. You will receive standard post-operative pain management.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?
There is no cost to participate in this study.

Will I be paid to take part in this study?
You will receive a $25 gift card after you complete all study activities. You will receive the gift card at your 6-week postpartum visit.

Who might benefit financially from this research?
The investigators have no financial benefit from conduct of this study. We have no financial affiliation with any company producing TENS units.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your reported pain ratings and number and type of pain medications will be recorded from your private hospital medical record. This information will be accessed by the research team. This information will be recorded under a study-assigned code number, not associated with your name or personal information. The survey you fill out at the end of your hospital stay will not include any personal information which could link your responses to your identity.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if I am injured during this study?

1. For research on subjects with a disease or medical condition: Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include skin and muscle irritation from the TENS device. In addition, it is possible that during the course of this study, new adverse effects of TENS that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Dr. Duzyj Buniak
Rutgers Robert Wood Johnson Medical School
Clinical Academic Building, Rm 2124
125 Paterson Street
New Brunswick, NJ 08901

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Dr. Christina Duzyj Buniak, Department of OBGYN - Maternal Fetal Medicine. 732-235-6632

If you have questions about your rights as a research subject, you can call the IRB Director at: the Rutgers Human Subjects Protection Program at (973) 972-1149 in Newark.

PERMISSION TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- *Hospital discharge summaries*
- *Medical history or treatment*
- *Medications*
- *Psychological testing, surveys or questionnaires*
- *Operative reports (about a surgery)*

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now, but change your mind later, for use of your information in the research, you must write to the researcher and tell him or her of your decision:

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How long will my permission last?

Your permission for the use and sharing of your health information will last until end of research study, which is anticipated to continue through December 2019.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____