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Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?

Document:
Consent

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TITLE: Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?

PI: Shaul Cohen, MD. Co-Investigator obtaining consent: Danielle Levin, BA

CONSENT TO TAKE PART IN A RESEARCH STUDY

This consent form is part of an informed consent process for a research study and it will give information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have any questions any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor (the principal investigator) or another member of the study team (an investigator) will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You understand that you are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Why is this study being done?

As part of the cesarean section procedure, you will be receiving anesthesia so that you do not feel pain during the surgery. A lot of patients experience the unpleasant side effect of nausea and/or vomiting as a result of the anesthesia. Doctors do not know which patient will experience these side effects. Nausea and/or vomiting during the cesarean section can negatively affect the delivery of the baby. Therefore, doctors try to prevent the patients from experiencing nausea and vomiting. There are different ways that doctors try to prevent nausea and vomiting, but they do not yet know what the best method of preventing nausea and vomiting is. This study is being done to help determine the best way to prevent nausea and vomiting during cesarean section.

Why have you been asked to take part in this study?

Many women experience nausea and/or vomiting during regional anesthesia for cesarean section. You have been asked to participate in this study to help us determine which medical treatment is best to combat these undesirable effects of regional anesthesia.

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Who may take part in this study? And who may not?

Pregnant women, ages 18 to 45, who are in good health and have no major medical issues, are invited to participate in this study. Patients requiring emergent cesarean delivery or those less than 37 weeks pregnant are not included in this study.

How long will the study last and how many subjects will take part in it?
You will be participating in this study from the time you consent to the study and until you are brought into the recovery room after your cesarean delivery. During the study, you will be asked to rate your nausea level at the following four points:

1) after administration of epidural medication
2) right after baby is delivered
3) after replacement of uterus
4) upon arrival to post-operative recovery room

A total of 240 patients will be enrolled into this study

What will you be asked to do if you take part in this research study?

If you take part in this research study, you will be randomly assigned to one of three groups. The randomization of patients has been done by a computer. To ensure your eligibility for the study, you will be asked questions regarding your medical history. Once we ensure you are eligible for the study and you sign the consent form, the investigator will assign you to the group on the list of randomized numbers. You will be assigned to one of the following groups:

If you are assigned to Group 1, you will receive scopolamine patch placement on the skin behind your right ear 1 hour before initiation of the regional anesthesia for the duration of surgery. A member of the research team will remove the patch from you upon your arrival to the post anesthesia care unit.
If you are assigned to Group 2, you will have an acupressure point P6 stimulator placed on your right wrist before being administered regional anesthesia. The device will be sending continuous electric stimulation to your forearm throughout the procedure at a level that is comfortable to you. The device will be removed from you at the completion of the cesarean delivery. Studies have shown that it is safe to stimulate this pressure point in pregnant women and may reduce a women's nausea/vomiting. However, the device was approved by the Food and Drug Administration (FDA) for monitoring how effective general anesthesia is working on a patient. We will be using this device off-label to determine if it is effective in reducing nausea and vomiting during your delivery.

If you are assigned to Group 3, you will receive both scopolamine patch and the device, as described above.

During the surgery, you will be asked to rate your nausea level as described above. If at any point during the regional anesthesia and cesarean section you experience nausea and/or vomiting, you will be administered the traditional rescue anti-nausea medications, regardless of what group you were assigned to.

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

The application of the acupressure point P6 stimulator has no known risks except for potential mild discomfort of the arm.

Common adverse effects of transdermal scopolamine patch include: dry mouth, dizziness, blurred vision, and dilation of the pupils. Rare but serious side effects include restlessness, confusion, memory problems, and hallucinations.

If at any point during the procedure, operation, or post-operative care, you will report that your nausea and vomiting is uncomfortable, you will be administered the rescue dose of traditional anti-nausea medications. This will occur regardless of what group you are assigned to.

Are there any benefits for you if you choose to take part in this research study?

By taking part in this study, you may experience less nausea and vomiting while delivering your baby.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

If you do not want to take part in this study, you will receive either metoclopramide, ondansetron, transdermal scopolamine patch, acupressure point P6 stimulation or transdermal patch with acupressure point P6 stimulation for nausea and vomiting which may occur during your cesarean section.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

Since you will be part of the study for only the duration of your surgery, it is unlikely that any new information will be obtained during your actual surgery. However, if there is new information obtained during your surgery, we will tell you about it.

Will there be any cost to you to take part in this study?

There will be no cost to you for participating in this study.

Will you be paid to take part in this study?

You will not be paid for participating in this study.

What will happen if you are injured during this study?

For risks you may experience from the nausea treatment, please refer to the question above called, "What are the risks and/or discomforts you might experience if you take part in this study?"

In addition, it is possible that during the course of this treatment, new adverse effects of transdermal scopolamine patch and acupressure point P6 stimulator that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment if you sustain personal injuries or illnesses as a direct consequence of the treatment. Your 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 you do not wish to take part in the study or if you later decided not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, 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 by verbally informing or in writing to Dr. Shaul Cohen at the following address:

Dr. Shaul Cohen
Rutgers Robert Wood Johnson Medical School
Department of Anesthesia
125 Paterson Street
CAB 3100
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.

How will information about you 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.

All data will be stored in a locked file in the office of the principal investigator with limited access. The link to the protected health information will be stored separately from the study files and will be destroyed after all the data has been collected and analyzed.

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

Who can you call if you have any questions?

If you have any questions about taking part in this study, you can call the study doctor:

Shaul Cohen, M.D.
Department of Anesthesia
732-937-8841

If you have any questions about your rights as a research subject, you can call:

IRB Director or IRB Chair
732-235-9806

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

What are your rights if you decide to take part in this research study?

You understand that you have the right to ask questions about any part of the study at any time. You understand that you should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

You have read this entire form, or it has been read to you, and you believe that you understand what has been discussed. All of your questions about this form and this study have been answered.

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

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

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?

- Medical history or treatment
- Medications

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 researchers 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
- The U.S. Food and Drug Administration (FDA)

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 research 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:

Dr. Shaul Cohen
Rutgers Robert Wood Johnson Medical School
Department of Anesthesia
125 Paterson Street
CAB 3100
New Brunswick, NJ 08901

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the research study.

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AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire 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 or this study have been answered.

Subject Name:_____
_____

Subject Signature:_____ Date:_____
_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____
_____

Signature:_____ Date: _____
_____