NCT02505984

Preventing Postpartum Depression with Intranasal Oxytocin

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Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Testing the Efficacy of Intranasal Oxytocin for the Treatment of Postpartum Depression

Principal Investigator: Sharon Dekel, Ph.D

Site Principal Investigator:

Description of Subject Population: English-speaking pregnant women between the ages of 18 and 50 who are at risk for postpartum depression and bonding failure in their third-trimester or early postpartum.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

A description of this clinical trial will be available on *http://www.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 Web site at any time.

Why is this research study being done?

We are doing this research study to investigate whether oxytocin can strengthen mother-infant bonding and can reduce the development of depression and posttraumatic stress disorder (PTSD) following delivery.

Oxytocin is a hormone that is naturally produced in the body. The U.S. Food Drug Administration (FDA) has approved oxytocin as an injection into the vein for induction of labor and control of post-partum hemorrhage (bleeding directly after delivery), but the FDA has not approved oxytocin to prevent or treat women with depression or PTSD related to childbirth, or to enhance mother-infant bonding. This study will use oxytocin as a nasal spray. This formulation is not approved by the FDA. This means that oxytocin nasal spray can only be used in research studies.

The proposed research will compare oxytocin nasal spray to placebo. Placebo is used in research to understand whether the results are due to the drug or other factors. The placebo spray will contain a salt solution rather than oxytocin but will look exactly like the oxytocin spray. During this study you may be given a placebo spray instead of oxytocin.

You are being invited to take part in this research study because you are pregnant or recently gave birth and may have risk factors for the development of depression following childbirth.

One hundred ten (110) women will be recruited for this study at MGH.

How long will I take part in this research study?

It will take you about 87 days to complete this study based on the average duration of a women's pregnancy (38 weeks). This will be from the 3rd trimester until approximately 60 days following the childbirth. There will be participation days with 2 study visits. One at 3rd trimester, Day 1 through 5 after childbirth, and 60 days after childbirth, approximately.

<u>For women participating in the Mothers Wellbeing Study:</u>
You will be in this study for approximately 2 months following childbirth. Your participation days will include one study visit and assessments at Day 1 during your postpartum hospital day and Day 5 remotely.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. (For women who participated in the Mothers Wellbeing Study, the study assessment will only begin after childbirth).

<u>Assessment #1 (approximately 32 weeks pregnancy): (only relevant for women recruited during pregnancy):</u>

We will ask you to undergo an assessment at MGH (60 minutes total). At this visit we will:

- ask you to complete a packet of questionnaires about your mental health, relationships, personality, sleep, and expectations about your upcoming delivery. You will not have to answer any questions you do not wish to answer.

- teach you how to self-administer the study drug in the form of a nasal spray, which you will begin using after your child is born.

- have 40mL (about 3 tablespoons) of your blood drawn for purposes related to this research study and related studies. These samples will be sent to a laboratory outside of Partners for analysis. You will have the option to waive your permission for blood drawing but still participate in this study.

Assessment #2 (8 hours after delivery):

Eight hours after delivery, while you are in the hospital, we will ask to complete additional questionnaires (about 25 minutes total) concerning your experience and emotional state.

Assignment to study group

We will assign you by chance (like a coin toss) to the oxytocin group or the placebo group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to oxytocin. You will have a 1 in 2 chance of being assigned to the placebo. You and the study doctor won't know which study group you are in, but the study doctor can find out if necessary.

Both oxytocin and placebo will be referred to as 'study drug' from here on in the consent form.

Initial study medication administration (8 hours after delivery):

Following the first postpartum assessment, and prior to feeding your baby, we will ask you to use a spray containing either the study drug oxytocin or the placebo, once into each nostril.

Continued study medication administration (up to 4 days after delivery):

You will then be asked to continue using the study drug as instructed every 4 hours including during the night over 4 consecutive days, right before feeding your baby. During the course of these 4 days, you will be asked to complete a diary to record your use of the study drug (10 minutes total). We will show you how to do this. We will call you after you have completed the assessment to see how you are doing with the study medication and the diary. We will also call

or text you remind you to use the spray during the 4 days, if you desire. Should you require further assistance, we may call you on additional days.

Assessment #3 (approximately 5 days after delivery):

You will be asked to complete questionnaires (30 minutes total) concerning your mental health, breastfeeding experience, and bonding with your baby. You'll be able to complete the questionnaires at home or in the hospital and mail them to us. We will call you after you completed the assessment to ask how your experience was and address any questions you may have.

Assessment # 4 (approximately 45 days after delivery):

You will be asked to complete the same questionnaires (40 minutes total) as well a questionnaire about personal growth here at MGH, as part of your regularly scheduled visit with the obstetrical staff. We will also ask you to participate in a 10-min video-clip interacting with your baby.

Storage of Video File

The video-clip will be stored as a digital file on a Partners-encrypted desktop computer and will be labeled only with a number. Once your data is no longer needed, the video-clip file will be destroyed.

Finally, you'll be asked to have 40mL (about 3 tablespoons) of your blood drawn for purposes related to this research study and related studies. These samples will be sent to a laboratory outside of Partners for analysis. You'll have the option to waive your permission for blood collection. After you completed the assessment, a member of our study team will answer any questions you may have about the study. If indicated and desired, you will be provided a mental health referral.

Blood Collection

Do you agree to let us collect your blood?

☐ Yes ☐ No Initials_____

We would like to store this blood sample and health information for future research related to postpartum depression. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The Principal Investigator will keep the key to the code in a locked file.

Do you agree to let us store your samples and health information for future research related to Postpartum Depression?

☐ Yes ☐ No Initials_____

If later you change your mind and want your samples destroyed, contact the Principal Investigator.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

Partners Alert System

Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

What are the risks and possible discomforts from being in this research study?

Risks of Oxytocin Nasal Spray

OXT nasal spray has been previously administered to women following childbirth. There are reports of mild complaints, which include: breast and nipple discomfort (13-20 out of 100 women) and uterine cramps (which may be painful) (5 out of 100 women). However, such side effects were also reported by women receiving a placebo spray. If you do experience painful uterine cramps, do not drive or operate machinery. Other uncommon side effects include bleeding from the nose after using the drug, unfamiliar sensation in the nose, and complaint about taste. Use of the drug by participants who experience postpartum depression was reported to transiently lower mood. A subsequent study, however, by the same group did not mention

these outcomes, nor with these outcomes reported elsewhere. Other rare undesired effects may include headache, nausea, or allergic dermatitis (a rash on the skin).

If our assessments indicate intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

Risk of an allergic reaction

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

Risks of completing questionnaires and video

You may experience emotional distress from answering questions concerning your mental health and during the short video-clip interacting with your baby. Such distress is expected to be short-lived (e.g., some may experience more anguish versus others in whom the experience may be short-lived). Should you experience any distress, you may call the Principal Investigator or the study psychiatrist.

Risks from having blood drawn

You may experience discomfort from having your blood drawn. Side effects may include bruising, swelling at the injection site, dizziness, infection and lightheadedness.

Unknown Risks

There may also be risks involved with participation in this study that are unknown at this time. If any significant new findings develop during the course of this study appropriate institutional reporting protocol will be followed, and the study protocol may be modified as required.

What are the possible benefits from being in this research study?

It is possible that you may not receive any direct benefit from taking part in this study. The use of the oxytocin nasal spray may strengthen your bonding with your infant and prevent the development of depressive and posttraumatic symptoms following your delivery. Therefore, use

of the oxytocin spray may benefit you and your baby. The use of oxytocin nasal spray may also facilitate successful breastfeeding, with subsequent benefit to the nutrition of your baby.

The information collected from this study may enable researchers to obtain knowledge on the effectiveness of oxytocin for enhancing bonding and preventing depressive symptoms in postpartum women.

What other treatments or procedures are available for my condition?

There are no current preventive interventions for women who might be at risk for developing postpartum depression and mother-infant bonding impairment. There are partially effective treatments for women who suffer from postpartum depression, and from mother-infant bonding impairment. These include antidepressant medication, psychotherapy, coaching, and baby massage. However, no current treatment has been found effective in treating both conditions. While antidepressants may reduce symptoms of depression, they may not help in facilitating bonding with your baby.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will receive payments in stages by checks mailed to the address you provide. You'll be paid $30 for the first assessment, $60 for using the drug and completing the second and third assessments, and $60 for completing the fourth assessment. The total pay if you complete all phases of participation will be $150. If you agree to have your blood drawn, you will receive an additional $30 ($15 per blood collection). Please understand that it may take several weeks for the check to arrive.

We will also cover your transportation costs to our laboratory and parking charges up to a limit of $25 per visit.

What will I have to pay for if I take part in this research study?

Participation in this study will not cost you anything. Study funds will pay only for certain study-related items and services such as the study drug and questionnaires. Your health insurer may be billed for, among other things, routine items and services you would have received even if you did not take part in the research (e.g. the blood sample taken at delivery). You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

Receiving Unencrypted Text Message Communication

Text messages by mobile/cell phones are a common form of communication. The Testing the Efficacy of Intranasal Oxytocin for the Treatment of Postpartum Depression research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messages may only be read during regular business hours unless communicated otherwise.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. You may be responsible for insurance co-payments or deductibles. We cannot provide funds for any outside treatment you may be referred to.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Sharon Dekel, PhD is the person in charge of this research study. You can call her Monday through Friday, between 9am and 5pm, at (617) 726-1352.

You can also call Roger Pitman, M.D 24/7, at (617) 726-5333, with questions about this research study. Calls to Dr. Pitman will be forwarded to his cell phone during non-business hours.

If you have questions about the scheduling of appointments or study visits, contact Sabrina Chan via email at schan27@mgh.harvard.edu or via phone at (603) 978-9660.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research

- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: 6.29.2020