Peripheral Oxytocin and Touch (POPP)

NCT05326776

Study Consent

Version date: 3/16/2023

University of California, San Diego
Consent to Act as a Research Subject

Effect of Peripheral Oxytocin on Touch Pleasantness and Pain

Introduction

Dr. Laura Case and associates are conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

The purpose of this study is to learn more about oxytocin in the skin and how it affects nerves that send pleasant touch or pain signals to the brain. The study will examine how individuals perceive gentle brushing and pain stimuli before and after a skin injection of oxytocin, compared to a placebo saline injection. This will help us understand the role of oxytocin in the skin, and whether it could be used to relieve pain. Participation in the study will not benefit you directly but may result in new knowledge that helps others.

This study has a total of two sessions, both at the Altman Clinical Research Institute (ACTRI) at UC San Diego. Participants who can become pregnant will undergo a urine pregnancy test at the start of each session. If the test is positive, you will be dismissed from the study. If you agree to participate in this study, you will be asked to complete questionnaires and make ratings of gentle brushing and a variety of pain stimuli. Photographs of your arm will be taken before and after the injection to document any reactions. Participation also involves receiving an injection of oxytocin or saline in the skin of your arm. In addition, you may receive a blood draw to measure levels of oxytocin, inflammation, and features of metabolism in your blood.

The most commonly expected risks of the study are discomfort from the pain stimuli that are administered and becoming bored with the questionnaires.

The most serious risks of the study include harm to a pregnant person or fetus from the oxytocin injection. These risks are extremely unlikely since we conduct careful screening for pregnancy and you may stop study procedures at any time.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?
You have been asked to participate in this study because you are a healthy adult. There will be approximately 20 participants at this site.

What will happen to you in this study and which procedures are standard of care and which are experimental?
In addition to the information at the beginning of this form, here are some additional details about will happen to you if you agree to be in this study,

Session 1: Session 1 will be split into two procedures.

1) After (only if) you have signed consent, we will retain your study screening information as study data. You will complete the series of study questionnaires via REDCap (online survey software). You will then be asked about your recent behaviors regarding caffeine, alcohol, food, smoking, exercise, and sleep. We will then introduce you to our thermode, the device we use to administer the heat stimulus. The thermode will be placed against your forearm with temperatures ranging from mild to painful, and you will be asked to rate the intensity of the temperatures. There will be a short break before starting the second procedure.

2) We will start by performing a blood draw (~10mL) to measure levels of oxytocin, inflammation and features of metabolism in the blood. Next, we will monitor your heart rate for 5 minutes. You will then be asked to make ratings of gentle brushing and a variety of pain stimuli, including mechanical, pressure, and heat. After the first series of ratings, you will receive an injection of oxytocin or saline into the skin of your forearm. Neither you nor the research technician will know which injection you are receiving. About 10 minutes after the injection, the series of gentle brushing and pain stimuli will be repeated.

Session 1 will take approximately 1 hour and 30 minutes to complete.

To ensure drug clearance, the sessions will be separated by more than two days according to the participant and experimenters' availability.

Session 2 will be a repeat of the second procedure in Session 1:

Prior to Session 2, you will be asked about your recent behaviors regarding caffeine, alcohol, food, smoking, exercise, and sleep We will start by performing a blood draw (~10mL) to measure levels of oxytocin, inflammation, and features of metabolism in the blood. Next, we will monitor your heart rate for 5 minutes. You will then be asked to make ratings of gentle brushing and a variety of pain stimuli, including mechanical, pressure, and heat. After the first series of ratings, you will receive an injection of oxytocin or saline into the skin of your forearm. Neither you nor the research technician will know which injection you are receiving. If you received oxytocin in Session 1 you will receive saline in Session 2, and vice versa. About 10 minutes after the injection, the series of gentle brushing and pain stimuli will be repeated.

Session 2 will take approximately 1 hour to complete.

All of these procedures are experimental and not for treatment purposes.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form,

1) Heart Rate Recording: Placement and removal of the leads for heart rate recording may cause some mild discomfort, local irritation, redness, or burning.

2) Skin Injection of Oxytocin and Saline: You may experience headache, facial flushing, and sensation of heart pounding. There may also be pain, redness, swelling, itchiness, bruising, or irritation near the injection site for 1-2 days. Rare complications include infection or accidental injection into a blood vessel or nerve. Injections will be performed by a licensed healthcare professional, and we will monitor blood pressure and oxygenation before and after the injection.

3) Blood draw: Approximately 20mL of blood will be drawn in total for this study. The main risks of drawing blood from a vein include discomfort, possible bruising and swelling around the puncture site, and (rarely) an infection or fainting from the procedure.

4) Heat Pain Stimuli: Reddening/darkening of the skin may occur with thermal stimulation. This is temporary and will not damage the skin.

5) Sensory Stimuli: The sensory stimuli may be slightly uncomfortable or cause brief skin irritation, but they will not break or damage the skin.

6) Confidentiality: There is a risk that information collected in our study could become known to individuals not involved in our study. Breaches in confidentiality could impact future insurability or employability. However, in our experience, this has not occurred with this type of research.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Are there risks to the reproductive system or a developing fetus?
The effects of oxytocin injection may pose some unforeseeable risks to a developing fetus. For this reason, you cannot participate in this study if you are pregnant. We ask that if you could become pregnant that you either abstain from sexual intercourse or use a reliable, effective contraception for this period, such as hormonal contraceptive, intrauterine device (IUD), diaphragm with spermicide, contraceptive sponge or use of condom by the partner. Because some methods of birth control are not 100% reliable, a urine pregnancy test will be required at the start of each session. If you have a positive pregnancy test, we will withdraw you from the

study. If you become pregnant or if there is any chance of pregnancy (e.g., late menstrual period), please contact the study personnel immediately so that we may provide medical assistance and counseling.

What are the alternatives to participating in this study?
You do not have to participate in this study. This is not a treatment study. The alternative to participating in this study is to not participate.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from these procedures. The investigator(s), however, may learn more about how oxytocin impacts affective touch and pain perception, with potential applications for treating pain.

What happens if you change your mind about participating?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be requested to inform the investigators and tell us why you are leaving the study. You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons your eligibility information changes, or the study physicians Dr. Engy Said or Dr. Nathaniel Schuster believes that it is in your best medical interest to leave the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time and travel, you will receive $80 for Session 1 and $60 for Session 2 for a total of $140. In addition, a free parking voucher will be made available for each study session.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All data will be processed in a HIPAA-compliant fashion to ensure confidentiality. Data are assigned a unique identification number and stored separately from your name and other identifying information. Digital data will be stored on both physically and software protected computers and will only be

accessed by study personnel from within the medical center. Any reference to individual participants in reports of this work will be encoded to preserve confidentiality.

Research records may be reviewed by the UCSD Institutional Review Board, The Food and Drug Administration (FDA) and The National Institute of Health (NIH), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from NIH. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding the project or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the research to release it.

Personal identifiers might be removed from the information or biospecimens collected as part of the research. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

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.

Will you receive any results from participating in this study?
You will not receive any results from participating in this study.

Who can you call if you have questions?

This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Laura Case at 858-246-4968.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____	_____
Subject's signature	Date
_____	_____
Signature of the person conducting the informed consent discussion	Date