Meets 2018 Common Rule Requirements

Naval Medical Center San Diego
CONSENT TO PARTICIPATE IN RESEARCH
Title: Premedication with Melatonin vs. Placebo in Patients Undergoing Interventional Pain Procedure
Principal Investigator: Dr. Rick Fisher, CDR, MD

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

The research team members at NMCSD are conducting this research study to learn about how melatonin can help decrease anxiety in patients before having an LMBB procedure. Your time on this study should not take more than 140 minutes. You will be assigned to either receive melatonin or placebo prior to your procedure and asked to fill out some questionnaires. Some risks of receiving the melatonin before your surgery include daytime drowsiness, headache, dizziness, transient depressive symptoms, mild tremor, mild anxiety, abdominal cramps, irritability, reduced alertness, confusion, nausea, vomiting, and hypotension. Your participation on this research study is completely voluntary and you may choose to remove yourself from this research study at any time. However, you may experience a decrease in pre-procedural anxiety and will be helping the research team at NMCSD learn more about ways in which we can improve patient care and safety in treating pre-procedural anxiety. You should speak to your physician about other methods of reducing your anxiety before your surgery.

Your decision will not affect your future care at Naval Medical Center San Diego. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are scheduled for an LMBB procedure at NMCSD. The purpose of this research study is to learn about the effectiveness of

melatonin for reducing anxiety in patients undergoing pain procedures. The duration of participation per visit is approximately 2 hours (140 minutes maximum). Your participation will conclude after 1 visit, which will coincide with your LMBB procedure.

There will be about 126 people taking part in this study overall, with about 63 participants to be enrolled at NMCSD, over a period of 5 years.

During the study, you will participate in one study visit. Your visit will begin 90 minutes prior to your scheduled LMBB procedure and conclude approximately 30 minutes after your procedure. Your total time in the study will not exceed 140 minutes.

This study is looking at the use of melatonin to reduce anxiety in patients undergoing an LMBB procedure. The use of melatonin prior to LMBB has not been studied before. This means that melatonin is considered experimental for reducing anxiety in patients undergoing an LMBB procedure.

At the end of this research study the clinical results, including research results about you will not be shared with you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have been done or this information collected as a part of your regular medical care.

The screening process for this study involves a medical chart review and brief questionnaire to determine if you are approved for an LMBB procedure at NMCSD and if you meet any criteria that would exclude you from participating (i.e. current pregnancy, infection, certain diseases, etc.).

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will: Be given informed consent. Then you will be randomly assigned by chance to receive a study medication. On the day of your scheduled procedure, you will be asked to take your assigned study medication and fill out 3 anxiety rating questionnaires, one each at check-in, pre-procedure, and post procedure.

You will be randomly assigned to one of 3 groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to any of the groups. You will be assigned to receive either 2 mg melatonin, 10 mg melatonin, or a sugar pill, also known as a placebo.

You will have a one in 3 chance of being in the placebo group. A placebo is an inactive, harmless substance, like a sugar pill, that looks like the research study medication but contains no medication.

This research study is a double blind study, which means that neither you nor the research team will know whether you are receiving the research study medication or a placebo. In the event of an emergency, there is a way to find out which one you are receiving.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of:

The risks and side effects of receiving melatonin prior to a procedure most commonly include daytime drowsiness (20%) headache (7.8%), and dizziness (4%). Other side effects that have been reported include transient depressive symptoms, mild tremor, mild anxiety, abdominal cramps, irritability, reduced alertness, confusion, nausea, vomiting, and hypotension. The risks and side effects related to the pain procedure (lumbar medial branch block) will be explained to you as part of your clinical care. Minimal discomforts are anticipated related to your underlying medical condition.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

It is not known whether melatonin can cause birth defects or other problems in an unborn child.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document. Additionally, you should advise your doctor and the principle investigator of this study if you are now breastfeeding or contemplate breastfeeding during the course of this study.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

The possible benefit to you as a research participant in this research study is that you may experience a reduction in pre-procedural anxiety. However, there is no guarantee that you will benefit from being in this research.

Additionally, others may benefit in the future from the information learned during this study. The possible benefits to others are improved patient care and safety in treating pre-procedural anxiety.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for reducing anxiety prior to your LMBB procedure. Alternative treatments and/or procedures that may be available to you include: (1) you may have your procedure as scheduled without the study medication or (2) your doctor may prescribe another

standard of care anti-anxiety medication. You should talk with your personal physician (if applicable) about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Dr. Rick Fisher, CDR, MC, MD, USN

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

This is an unfunded research study.

13. LOCATION OF THE RESEARCH:

Naval Medical Center San Diego and Naval Medical Center Portsmouth

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

No study personnel have any personal or financial interests associated with the conduct or outcomes of this research study.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing

regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from the Naval Medical Center San Diego, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: A study key will be used to link your name with a study ID. All research data collected from you will be coded with this ID and will not contain your name or other identifying information about you. The study key will be kept separate from any forms containing personal information and any study data. Informed Consent forms and the study key will be the only forms that contain identifying information and will be physically secured in a locked office. Only trained research personnel will collect Informed Consent and handle sensitive information, in accordance with NMCSD guidelines. All electronic databases will be password protected and stored on secure, DoD servers.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Research Staff, the Institutional Review Board (IRB) of the Naval Medical Center San Diego, and the Department of Defense (DoD) will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part. You will be The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. This study, study procedures, and study participation will not affect your military career in any way. This includes no effect on your duty status, service eligibility, and opportunity for promotion.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify Dr. Rick Fisher at 619-871-9986 to ensure your timely removal from the study. If you do not follow these procedures, you may not have your data withdrawn from the study efficiently.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

19. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Dr. Rick Fisher, CDR, MD
Phone: 619-871-9986
Mailing Address: 34800 Bob Wilson Dr., San Diego, CA 92134

Naval Medical Center San Diego Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.
Phone: (619) 532-5524

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the Naval Medical Center San Diego IRB Office at:

Institutional Review Board	or	Clinical Investigation Department
(619) 532-9927		(619) 532-6099

California Experimental Subject's Bill of Rights

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

(i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date