Banner
University Medicine

The University of Arizona Consent to Participate in Research

Study Title: The Effect of Light Therapy on Chronic Pain

Principal Investigator: Mohab Ibrahim, MD., Ph.D.

Dr. Mohab Ibrahim has disclosed an outside interest in Luxxon and Luxxon Therapeutics to the University of Arizona. Conflicts of interest resulting from this interest are being managed by The University of Arizona in accordance with its policies.

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

Why is this study being done?

Chronic pain is a very difficult and complex medical problem. The current drugs available to treat chronic pain are usually strong opioids. Even with high doses of opioids, the chronic pain may not be well controlled. Additionally, high doses of opioid may result in significant side effects. This study is designed to investigate the possibility of better chronic pain control by exposure to certain colors of light.

What will happen if I take part in this study?

If you decide to participate in this study, you will be asked to sign this consent form. Before you are included, the following criteria must be met.

Inclusion Criteria:

- Male or female ages 18 – years and older, capable of understanding English and able to comply with outcome of the instruments used
- Have peripheral neuropathy from HIV or chemotherapy
- History of fibromyalgia
- Headaches
- Chronic pain
- 10 week history of average pain score of 5 or more at baseline evaluation

Exclusion Criteria:

- Receiving payment for their pain treatment (e.g. disability, worker's compensation, auto injury in legal process or pending legal process
- Are incarcerated.
- Unable to read English and complete the assessment questionnaires
- Addictive behavior, severe clinical depression or psychotic features

Once you have signed the informed consent form and have met all eligibility criteria to participate, the following procedures will be conducted. During the initial visit, we will collect several pieces of data from you that are considered part of the routine care, this information will also be used for research purposes. Initially we will ask you to provide your age, gender, work status, disability status, type of work, whether a previous pain physician has evaluated or provided treatment in the past, if there is any ongoing litigation, a detailed description of the pain (burning, electrical, shooting…etc.) and its location. If you are being seen in the clinic for your normal care a detailed physical examination assessing the motor strength of the upper extremities, sensation to light touch and reflexes that is part of the standard of care will be provided for you. You will be asked to give a numerical value for your pain (a scale from 0-10 where 0 is no pain and 10 is the worst pain imagined). Several questionnaires will be provided for you to complete which are not standard of care. These questionnaires will be explained to you at your baseline visit and will take approximately 12 – 20 minutes to complete. If you are being evaluated via telephone call, the same questions will be conducted.

You will be assigned to either a white, green or the crossover light group. Once you are assigned a light group, you will be given a strip of LED light that corresponds to your color group. You will be asked to use the LED strip in a dark room in your house every day for two hours for 10 weeks. You may also be assigned to the crossover group in which you will be given a white light for 10 weeks, there will be a wash out period of 2 weeks, where you will not be required to be exposed to the white light, then crossover to the green light for ten weeks. The study start-date and the outcome assessment timeline will begin from the date of your first exposure to the assigned light. You will be asked to complete your weekly questionnaires and daily logs, these will be given to you on your first clinic visit or sent to you if you live out of town. There will be several follow up appointments as detailed below.

For the follow up clinic visit or phone call (Week 10), data similar to the information gathered at the initial visit will be collected. The description of the pain (burning, electrical, shooting…etc.) and its location will be reviewed. If you are being seen in the clinic, a physical examination assessing for pain and sensation to light touch that is part of the standard of care will be provided for you. At the end of the study, you will be asked to return the LED strip, your logs and questionnaires.

The following is a schedule for the expected visits from this study:

- Baseline examination and questionnaires will be completed, office visit or phone assessment
- Day 0 – Initial exposure to assigned light.
- Week 3 (+/- 1 week) – follow-up phone call.
- Week 6 (+/- 2 weeks) – follow-up phone call.
- Week10 (+/- 2 weeks) - follow-up office visit or phone call.
- Week 12 (+/- 2 weeks) - follow-up office visit, for crossover subjects only.
- Week 22 (+/- 2 weeks) for crossover subjects only - follow-up office visit or phone call

You will be asked to complete the questionnaire about your pain (EQ-5D) and hand, send, email or fax in all your questionnaires and daily logs.

There is an optional saliva test to check for melatonin and optional blood draws to test for inflammatory mediators. These tests are optional and are explained at the end of this consent form.

How long will I be in the study?

The study start-date and the outcome assessment timeline will begin from the date of your first light exposure. The study is expected to be 10 – 22 weeks long, depending on the light group you've been assigned.

How many people will take part in this study?

Up to 200 subjects that have peripheral neuropathy from HIV or chemotherapy, history of fibromyalgia, headaches, chronic pain and 7-day average pain score of 5 or more will be enrolled in this study.

Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

We may ask for an explanation to be included in any publication that may result from the study, but is voluntarily.

What risks, side effects or discomforts can I expect from being in the study?

There have been no reported side effects of exposure to these wavelengths of light. There is virtually no risk known.

Risks for optional blood draws are minor, this may include hematoma at the puncture site, discomfort at the puncture site, bruising and infection.

What benefits can I expect from being in the study?

You may or may not benefit as a result of participating in this study. You may notice improved pain intensity, decreased analgesic requirements, or decreased side effects from analgesics.

What other choices do I have if I do not take part in the study?

You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate you will have access to regular pain management as covered by your medical insurance.

Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups:

- The University of Arizona Institutional Review Board
- Banner – University Medical Center South (B–UMCS)
- Office for Human Research protections or other federal, state, or international regulatory agencies

Banner – University Medical Center South (BUMCS) has an electronic medical record system. Medical services and test results completed by BUMCS for this research project will be placed in your medical record (such as study questionnaires). If you do not have a BUMCS medical record, one will be created for you. It is necessary to create a medical record for services completed by BUMCS so that BUMCS can appropriately bill for the service. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation in this study.

Your medical record will be flagged to note that you are in a research study. You will also have a research record that is separate from your medical record. Your research record may contain additional information that is not included in your medical record.

IRB, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data, without violating your confidentiality, to the extent permitted by applicable laws and regulations and that, by signing the consent document, you are authorizing such access.

If the trial results are published, your identity will remain confidential.

What are the costs of taking part in this study?

There are no anticipated additional costs for you to be in this study, except for your time and cost of transportation to and from the pain clinic for follow-up appointments. Regular medical care performed while participating in this study will be billed to you and / or your insurance company as usual.

Will I be paid for taking part in this study?

There is no monetary compensation for participating in this study

What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

When may participation in the study be stopped?

The study may be stopped by the investigator for any of the following reasons:

1) Violation of any of the inclusion criteria.
2) Aggressive behavior towards the pain or palliative clinic staff.
3) Development of new or discovery of already existing medical condition(s) that was not there during the initial screening if such condition(s) may interfere with the study.
4) Sustaining an injury that may require additional pain medication or may interfere with accurate gathering of the data.
5) Hospitalization for any reason that prevents you from exposure to the assigned light as instructed.
6) Any situation that hinders your access to assigned light and follow-up appointment.
7) Refusal to accurately filling pain diaries and reporting them honestly to the pain clinic staff.
8) Testing positive for illicit drug use, you will not be tested for research purposes, but if you volunteer this information or we see it in your records, you will be withdrawn from the study

Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the study doctor. Mohab Ibrahim, MD, PhD at 520-874-7246.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at http://research.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Mohab Ibrahim, MD, PhD at 520-874-7246, Department of Anesthesiology, 1501 N. Campbell Ave. Tucson Arizona 85724-5114.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Protected Health Information

For you to be in this research study, we need your permission to collect, use and share health information that identifies you. If you sign this form, we will collect, use and share your health information until the end of this research study, which may be after your direct participation in the research project ends. If you decide not to sign this form, you cannot participate in the research study. Whatever decision you make about this research study will not affect your access to medical care.

Information to be used includes things learned from the procedures described in this consent form. Other information may be collected, including, but not limited to, date of birth, past medical and surgical history, current medications, radiological images and allergies. This may also include information about HIV, or treatment for drug or alcohol abuse or mental health problems.

We may use and share your health information with people involved in this research, others who administer, oversee, regulate, or work with us on research. In addition, people involved with your future medical treatment (including your insurance plan) may become aware of your participation and of any information added to your medical record as a result of your participation in this study.

We will use and disclose your information only as described in this form and in the relevant Notice of Privacy Practices provided by the individual or entity who holds your medical records and/or other related information; however, people outside the University of Arizona who receive your information may not be covered by this promise or the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") or other applicable federal and state laws. We try to make sure that everyone who needs to see your information keeps it confidential, but we cannot guarantee this.

The use and disclosure of your information has no time limit, you can cancel your permission to use and disclose your information at any time by contacting the Principal Investigator of this study in writing. Please include the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page 4 of this form. Please note that we may continue to use and share the information we have already collected about you, but we won't collect any further information about you for the research study.

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.

Optional Research Activity

Optional research activity is part of this study, if you choose to participate in this optional activity, your PHI shall be included for this optional study.

By initialing the boxes, you agree to allow your PHI to be used and/or disclosed for the optional study activity as describe in this consent form. You also give your permission to the study doctor and his/her staff to conduct the optional assessments.

☐ OPTIONAL saliva samples for melatonin analysis. If you agree we will ask you to provide 2mls of saliva every 30 minutes for 3.5 hours at baseline prior to your light exposure and at the end of the study for a total of 14 samples. We will provide you with collections tube for saliva samples at no cost to you. We will ask you to return the samples the day after collection. If you're in crossover study, you will be asked to provide 2 mls of saliva every 30 minutes for 3.5 hours at baseline prior to the white light exposure and again at the end of white light exposure. Then again prior to exposure of the green light and at the end of the green light exposure of a total of 28 samples. Samples will be stored in a -80 freezer till processed and analyzed. They will not be stored for future studies.

☐ OPTIONAL blood draws to look for inflammatory mediators, increased anti-inflammatory mediators and endocannabinoids. For the crossover group, this will be done a total of four times. The first draw will be before starting the white light. The second draw will be after finishing the white light. The third draw will be before starting the green light. The fourth draw will be at the end of the green light. Each draw will be 8 mls (1.6 tsp) for a total of 32 mls (6.5 tsp). For the other two arms, 8 mls will be collected the start of the light exposure and at the end of the light exposure for a total of 16 mls (3.2 tsp). Samples may be stored for up to 3 years for future study related analysis. Samples will be stored anonymously.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	Signature of subject
	Date

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Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent
	Date