RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Effect of Topical Chylobinoid Cream on Pain and Function Scores for Hallux Disorders: A Randomized Controlled Trial

Sponsor(s): Rush Department of Orthopedics

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to determine if chylobinoid (CBD) cream can decrease pain in two degenerative conditions of the great toe: hallux valgus and hallux rigidus. CBD is an active ingredient in many products. CBD cream is an investigational product not yet approved by the FDA for treatment of osteoarthritic pain. The term "investigational" means that the product has not been approved by the U.S. Food and Drug Administration (FDA) and must be tested to see if it is safe and effective treatment for this disease or condition.

If you agree to participate in this study, your participation may last up to four weeks and you will be asked to complete a daily pain journal, a weekly survey regarding your toe pain and function, and return for one clinic follow up. During the study period, you will be asked to use a topical cream as needed on your involved great toe, in addition to any other clinically indicated treatment such as orthotics or physical therapy. The CBD and placebo cream will be provided by the Department of Orthopaedics.

For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are risks to you for participating in this study. In this study, there is a risk that your pain will not be improved by the CBD or placebo cream. The CBD and placebo cream will look exactly alike; however, the placebo cream contains inactive ingredients designed to have no real effect. The placebo cream is used in this study to determine whether the CBD cream has a real effect. The ingredients of the placebo cream are as follows: Butyrospermum parkii (shea butter), caprylic/capric triglycerides medium chain triglycerides (MCT oil), food coloring to match the CBD oil. There will be 345 grams of shea butter and 62ml MCT oil per batch.

Additionally, a risk of participating in this study is the potential for a breach of confidentiality. The research involves the collection or study of existing data, documents, and/or records (for medical history purposes). Data that develops as part of your routine care (such as lab results, medication dosages, etc.) will also be collected for this study. Once data is collected, that data will be de- identified for the data analysis and manuscript preparation. This means that no one outside of your study doctor and his research staff will have access to any of your identifying information, such as your name or birth date.

You may benefit from taking part in this study. Studies on CBD derivatives in both animals and humans show that it may be of benefit to people with your condition or it may be as good as standard therapy with fewer side effects. However, because individuals respond differently to therapy, no one can know in advance if it will be helpful for you.

If you are assigned to treatment with placebo, you are not expected to get any health benefits from participating in this study. You should not expect your condition to improve as a result of participating in this study.

There are other options available to you if you decide not to participate in this study. You may choose another form of treatment or care for your hallux rigidus or hallux valgus without being in a study such as orthotics, steroid injections, oral anti-inflammatories, and physical therapy. CBD cream is available over-the-counter, and you can receive this treatment without being enrolled in the study if you desire. You should discuss these other options with your study doctor.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have significant pain as a result of your hallux valgus or hallux rigidus, and you have not had a prior operation on your first metatarsal (bone in the foot just behind the big toe).

How many participants will take part in this study?

Approximately 54 participants are expected to take part in this study here at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?

If you agree to be in this study, you will be asked to participate in the following activities:

- You will be randomized to either receive CBD cream or a placebo cream. You and your doctor will be blinded to the type of cream that you receive.
- Apply the given cream to your involved great toe as many times as needed
- Complete a daily pain journal for the four weeks of treatment
- Complete a weekly email survey regarding your foot pain and how the pain impacts your daily life (Foot Function Index)
- Return to clinic after four weeks of treatment, and answer 2 brief questions regarding the treatment
- Return your unused cream to the study personnel

Will your information be used for research in the future?

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

What are the risks and discomforts of participating in this study?

There is a chance that you do not see improvement of the pain related to your hallux valgus or hallux rigidus if you are in the placebo group. This will not place you at increased risk for progression of your disease. While CBD is not FDA approved for use in inflammatory/arthritis conditions, it has been FDA approved for other conditions. There are no known side effects associated with topical use.

This study involves collection information from your medical records and surgery. The only risk is the release of confidential personal health information. We will take every precaution to protect your information. All data collected will be protected on a password protected encrypted computer. Information identifying subjects will not be released to the public. Once all data is collected and analyzed we will remove all identifying data.

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Are there any anticipated pregnancy risks?

If you are pregnant you cannot take part in this study. Women with known pregnancy will be excluded from the study. In the routine care of foot and ankle patients, a pregnancy test is not administered prior to these radiographic tests. If you already know you are pregnant, or think you may be pregnant, please inform the study staff, and you will not be included in the study to avoid any even minimal additional radiation.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. If you chose to leave the study, you will be required to return the treatment cream which was given to you at the beginning of the study. There are no safety concerns for stopping the study early. The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Lee, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Lee and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Age, weight, other medical comorbidities, pre and post treatment pain scores, severity of hallux rigidus or hallux valgus, other prescribed treatment modalities, physical exam results, and Foot Function Index Scores.

Dr. Lee and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Lee is not required to release to your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept

indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Lee at 1611 W Harrison St, Suite 300, Chicago IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All study data will be stored on a secure serve at Midwest Orthopedics at Rush. All stored data will be deidentified. Study materials will be password protected and only available to the study team.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

What are the costs to participate in this study?

The CBD and placebo cream will be provided to you free of charge by the Department of Orthopaedics. All other costs that are part of your usual medical care, such as clinical visits, surgery, and any tests associated with these visits will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this study.

Will you be paid for your participation in this study?

You will not be paid for being in this study.

Investigator Dual-Role

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Elizabeth Terhune (Research Coordinator) at (801) 824-9805 or email her at elizabeth_b_terhune@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Lee in writing at the address on the first page. Dr. Lee may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the person signing the form has done so voluntarily.

Name of Witness/Interpreter	
Signature of Witness/Interpreter	Date of Signature