Consent Form

Analgesic Activity of Topical Pain Cream in Patients With Chronic Pain

Study Performance Site:

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Contact Person:

This is a clinical research study to evaluate the pain relief effects of one of two topical creams, cream A or cream B and compare them to the only currently available topical pain medication Voltaren gel.

Background:

Pain is a major reason patients visit a physician. About 20% of patients visiting a physician have experienced pain for more than 6 months. The management of pain requires action and the effective use of medications to limit the possibility of addiction. Pain creams using non opiate ingredients may be a useful approach. This study aims to evaluate the effects of two pain creams and compare their effect to topical pain gel available, Voltaren gel.

Study Design

If you have chronic pain in a region of the body that a cream can be applied to the skin you are eligible for the study. You can receive one of the new creams (cream A or B) or a prescription medication (Voltaren gel) depending on whether your insurance covers the cream expense. Your physician will decide which one of the creams A or B is better suited to your condition based on your history. You will be instructed how to apply the cream by your physician (it may be from 1 to 4 times per day and the area you spread the cream on will be told to you before you start treatment). If your insurance coverage does not pay for Cream A or Cream B, you can purchase the medication, or receive standard topical therapy Voltaren Gel, which will be provided free of charge for the first two months of the study. If you and your doctor think the Voltaren is working, you can continue in the study and purchase the Voltaren Gel, or if insurance covers this medication, have the cost covered by insurance.

Initially you will be evaluated by the physician, asked to sign the consent, if you are eligible for the study you will then be given 3 short pain questionnaires to fill out. Then you will be assigned one of the creams and asked to return at 4 weeks, 8 weeks, 12, 16, 20 and 24 weeks for follow up with repeat questionnaires, and examination. You may be seen more frequently by your physician, depending on your medical condition. The main measure of whether the cream or gel works will be the assessment scale called "global assessment" performed at 8 weeks after starting the cream or gel therapy. You are asked to report any medical problems that occur promptly to your physician. Please report

stopping any medication or any increase or decrease in any pain medications to your physician. The study will last for 6 months (24 weeks). At the end of 6 months you can continue to receive the Cream A or Cream B as part of an "open label" continuation study being evaluated at the end of the additional 6 months

Inclusion Criteria to take part in the study.

1. 18 to 85 years of age – males and females
2. Chronic extremity, joint muscular skeletal, numbness, burning or topical pain lasting for more than 2 months, interfering with daily activities, work or sleep.
3. Any disease (cardiac, renal, hepatic) must be under control.
4. No skin lesions (blotches, "weeping skin", holes) at the site of where the cream or gel is put on.
5. Able to understand this consent form.

Exclusion Criteria

1. Pregnant or lactating females or women of child bearing potential, not on Effective Contraception.
2. Use of other topical or transdermal medications. You can be in study if off these medications for 2 weeks.
3. Allergy to local anesthetics or other medications when they are put on your skin.
4. Surgery with a scar at site of pain where cream or gel needs to be put on preventing drug absorption.
5. Unable to comply with the study procedures.

Risks

Both cream A and Cream B have a number of ingredients in them that are given orally. In this study they are ground up and used as a topical cream. These medications can cause skin rash, allergy, and be absorbed in the body giving general effects that can be bothersome, like fatigue and dizziness, or could lead to a low blood pressure, fainting, or confusion. The amounts of the medication are selected that should not cause problems, but it is possible that you absorb too much medication through your skin. Additionally, if your insurance does not pay for the creams, you will be given the Voltaren gel by prescription and may need to pay for the medication (after the first two months) if insurance does not cover. Participation in the study is always voluntary.

Benefits

You will be receiving repeat measurements of the extent of pain relief and this may help your physician chose the best pain relief medication. Also, you will have the opportunity to receive one of the two pain relief creams provided through this study.

Alternative to Participation

You may choose not to participate and there will be no adverse consequences for your treatment by your physician.

Confidentiality:

All information collected will be kept confidential. No personal or medical information will be made public. The study results may be reviewed by the Sponsor of the study. The personnel of the American Institute of Therapeutics

that manages the study, the Investigational Review Board that reviewed the study, the Food and Drug Administration of the United States, as well as the National Institute of Health that supervises all clinical research in the United States. Also, states and local health inspectors may review our study records. All these agencies maintain the strictest standards of research volunteer record confidentiality, as does the American Institute of Therapeutics, the manager of the study.

Compensation and Indemnification

There is **no** compensation provided to you for participation in this study. You will receive a stipend for expenses incurred in traveling to the physician's office monthly, $15 per month for 6 months that will be paid every second month ($30) by a check sent to you ($90 in total).

If you are injured by participating in this study you must notify your physician immediately if you are injured. Acute medical emergencies will be treated first at the study site and if need be, you will be transferred to the nearest hospital for further medical care. If the problem arises at home, call your doctor immediately, or if a serious medical emergency call 911 or the appropriate emergency number in your area. In the event a research participant has a research related injury, the Sponsor of the study will be financially responsible solely for acute medical care for injury as a direct result of the study medication (cream A or cream B).

Termination:

As a research participant, you may terminate the study at any time. We ask that you provide a reason for termination and state if you have been injured. You will have no other obligations. Your records will be kept confidential and if you would like referral for future care or advice, the study personnel will be glad to assist you. If in the opinion of your physician you are felt not to benefit from the study, or you have not complied with your physician's instructions or instructions of other study personnel, you may be terminated from the study. In no way will this prevent future care by your physician outside the study.

No funds have been set aside, nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research. You do not give up any of your legal rights by participating in the study.

Contact

If you have any questions regarding your rights as a participant in the study, you may contact Dana Gonzales at Solutions IRB (the organization that oversees the protection of study participants) at 1-855-226-4472 or email participants@solutionsirb.com., or the American Institute of Therapeutics at 847-735-1170, where Dr. John Somberg, the managing Principle Investigator can be reached.

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For Emergencies:

Contact your doctor _____ at _____, or the American Institute of Therapeutics at 847-735-1170. If a **life threatening** serious **emergency** call **911** or go to your nearest hospital.

I have read the 7 page consent form and have agreed to participate in the cream study.

_____ _____ _____ _____
Volunteer Signature Date Witness Signature Date

_____ _____ _____ _____
Printed Name of Volunteer Date Witness Printed Name Date

_____ _____
Person obtaining consent signature Date

_____ _____
Printed name of person obtaining consent Date

Study Performance Site Number _____

Study Site Contact Person _____