Heat Application to the Quadriceps Musculature and Its Effect on Pain Following a Total Knee Arthroplasty

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The Idaho Clinic

IRB: 22-01

7/13/2022

Saint Alphonsus
RESEARCH INSTITUTE

CONSENT AND AUTHORIZATION FOR RESEARCH PURPOSES

Note: Recommendations and instructions are provided in italics. As you insert text specific to your study, please remember to remove the italicized text provided.

Heat application to the quadriceps musculature and its effect on pain following a total knee arthroplasty.

Principal Investigator: Cole Adams

Co-Investigator(s): Dr. Brad Daines, Dr. Jared Armstrong

Note to Patient

- **This informed consent form may have words that you do not know. Please ask the study doctor or other study staff to make clear any words that you do not clearly grasp.**
- **Before agreeing to take part in this study, you should carefully read this informed consent form. You may take an unsigned copy of this informed consent form to review and talk with your family and friends.**
- **Before you decide to take part in this research study, it is vital for you to know why the research is being done and what it will involve. Take time to decide whether you wish to take part.**
- **You will receive a signed and dated copy of this informed consent form for your records.**

Study Purpose

The purpose of the study is to evaluate if using heat on the quadriceps musculature will decrease symptoms after a knee replacement. You are being asked to be in this study because you are undergoing a total knee replacement. The study will help researchers see if pain, range of motion, and other symptoms decrease with indirect heat application.

Study Procedures

Pain, stiffness, symptoms, quality of life and function of the knee will be evaluated utilizing patient-reported measures and range of motion. Patients will be assessed using the Knee Injury and Osteoarthritis Outcome survey (KOOS Jr), Visual Analogue Scale (VAS) and PROMIS. Patients will be given these surveys during their two and six week check-in with the surgeon. In addition to these patient-reported measures, we will also be tracking range of motion (ROM) and opioid usage. The data will then be collected via the patient's electronic health record, or by the researcher directly. The

treatment group will be given a written order to apply heat to their quadriceps at least three times per day for 10-15 minutes each. This can be done in four hour increments or when patients symptoms begin to worsen. They will receive a rice sock for heat application. The control group will not be withheld from heat application, but will not be instructed to do so. They will instead follow the current standard of care as advised by the physician.

Number of People in the Study
We expect to have 150 people or more at The Idaho Clinic.

Risks, Discomforts and/or Potential Side Effects of Participation
Being in this study may involve risks that we do not know about or can predict. One risk that can be seen is overexposure to heat possibly causing burning of the skin. This risk will be minimized by following instructions given with the rice sock. Another risk that comes with this research is due to a possible confidentiality breach. This risk is minimized by the researcher following the current HIPAA guidelines, and accessing the medical information at the medical center.

Benefits
We cannot promise benefits to you for being in the study, but the information we learn may help future researchers and patients.

Costs & Payments
While you are in this study, all health care services and tests that are not part of your usual care will be given at no cost to you. Non-study or sub-study related usual care that you get will be billed to your insurer and/or to you in the regular way. You should learn before taking part in this study or sub-study which part of your health care will be free, which costs will be paid by your insurer, and which costs you will need to pay. If your health insurer or Medicare requires a co-payment, co-insurance, or deductible, you will be responsible for making that payment. The participants will not receive any form of reimbursement for participating in this study.

Alternative Treatment
You do not have to be in this study. Your care will not be changed in any way if you choose not to be in the study. If you do not want to be in this study, you may choose to follow the current standard of care as recommended by the physician.

New Information
We will tell you any new information we learn that may change your decision to stay in the study.

Removal from Study
The researcher may remove you from the study at any time. Reasons for doing so may be non-compliance with the guidelines, or dangerous usage of the provided equipment.

Voluntary Participation
Being in the study is your choice. If you decide to be in the study, you may stop at any time and without giving a reason.

Your choice not to be in or stop being in the study will not change your care or your benefits in any way. You can still get the usual care that is available to you. It will not change the relationship you have with your care providers if you choose not to be in the study.

If you decide to stop being in the study please contact Cole Adams at cadams@s.Idahocom.org.

Contact Information
You may call the researcher, Cole Adams at (970) 618-3142, or alternatively email him at cadams@s.Idahocom.org if you have any questions.

If you think you may have been hurt from being in this study, if urgent, please call 911. Other questions or concerns can be answered by the researcher as listed above.

Confidentiality
All information in this study is kept private. Your medical record will remain private and information secured using a statistical software called SPSS. Only people who work on this study will have access to your information. Results of this study may be presented or published. Your name will not appear in any publication or presentation.

People from the Saint Alphonsus research office, and the NIH may inspect records that name you. Your name and other personal records will be kept private.

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.

Your Rights
You can call the Saint Alphonsus Research Integrity Office at (208) 367-8897 or (208) 367-2233

- If you have any questions about your rights as a person in a study
- If you wish to talk about study issues, but not with the researcher

Research Related Harm
If you are hurt from being in this study, medical care is offered at Saint Alphonsus and other medical centers.

Saint Alphonsus does not have a program to pay you if you are hurt or have other bad results from being in the study. The costs for any aid or care would be charged to you or your insurance company. Since this is a research study, some health insurance plans may not pay for the costs.

Authorization for use of Your Protected Health Information
You are being asked to let Saint Alphonsus, The Idaho Clinic, and its staff use and/or disclose your health information for research. Staff will follow state and federal laws for the privacy of health information. Saint Alphonsus is asking you to allow use of your health information as part of a research study. This study may involve giving you treatment. This health information may contain opiate usage, pain levels, range of motion, as well as other symptoms you are experiencing.

Others who may have access to data for this research project include, but are not limited to the Saint Alphonsus Institutional Review Board (IRB), Food and Drug Administration (FDA), the Office of Civil Rights (OCR), the Office for Human Research Protection (OHRP), the study sponsor or approved staff at Idaho College of Osteopathic Medicine and The Idaho Clinic.

Your health information may be re-disclosed and no longer guarded by these rules if the person or party that gets your health information is not a health care provider or a health plan covered by federal regulations.

This Authorization is in use until it is revoked or runs out.

Please know that you may say no to this authorization. You do not have to sign. You may cancel this Authorization at any time by sending written notice of your choice to:

Saint Alphonsus Regional Medical Center
Attn: HIPAA Privacy Official
Integrity and Compliance Program
1055 N. Curtis Road, Boise, Idaho 83706

Data received before cancelling the authorization may still be used for this study.

You may look at and/or copy any of your health information that is used or disclosed under this authorization. Access to this information may be suspended until the research study is done. Revoking this authorization may result in the end of study treatment for you.

Patient Consent

I know that my joining this study is fully my choice. I have the right to stop participating in the study any time and seek conventional medical treatment. My signature below shows that I have decided to take part in the study after being told the risks, benefits and other choices. I have read the information given to me. I have had the chance to ask and have my questions answered.

I understand that the data gathered during this study may be used and released only when such use and release does not break any laws and I accept that the National Institute of Health, Food and Drug Administration (FDA), or other sponsors may check my records.

I understand that a copy of the consent and authorization form I am signing will be returned to me.

_____
Participant name (printed)

_____ _____
Participant Signature Date

Name of Person Obtaining Consent/Authorization

Signature of Person Obtaining Consent/Authorization Date

Use Legally Authorized Rep signature lines only if study population is unable to provide informed consent. (Contact Research Integrity at 367-8897 if any questions)

Name of Authorized Personal Representative

Signature of Authorized Personal Representative Date

If the participant is unable to give authorization and consent, please indicate the legal representative's authority to act for the individual (check ONLY one):

Spouse
Adult (18 years of age or over) for his or her parent
Individual with power of attorney
Guardian appointed to make medical decisions for individuals who are incapacitated