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IRB NUMBER: 210146080817

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY
DIVISON OF UROGYNECOLOGY AND RECONSTRUCTIVE SURGERY
DIVISION OF MATERNAL FETAL MEDICINE

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: The Predictive Value of the Active Straight Leg Raise on the Efficacy of a Sacroiliac Joint Belt in Posterior Pelvic Girdle Pain during Pregnancy

THE APPROVAL FOR THIS PROJECT EXPIRES ON 06/27/2020.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

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PURPOSE OF RESEARCH: You are being asked to participate in this study because you have pelvic girdle pain (PGP) also commonly known as "sciatica" in your pregnancy. The use of a pelvic belt may help to reduce PGP. A pelvic belt is a flexible belt that wraps around the hips and pelvis to provide support and stability to the joints.

The purpose of this study is to see if pelvic girdle pain can be more effectively treated with a type of pelvic belt called a sacroiliac joint belt.

This research is sponsored by the Scott F. Nadler PASSOR Musculoskeletal Research Grant of the American Academy of Physical Medicine and Rehabilitation Foundation.

Approximately 70 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will first be asked to read and sign this informed consent document, and a copy of the consent form will be given to you. If you agree to participate in the study, you will be asked to attend two study visits.

Visit 1: At Visit 1, which can take place the same day you sign the consent form, you will be given a set of questionnaires to complete that ask about your pain, medical history, and activity level. The study physician, Dr. Colleen Fitzgerald, will conduct a physical exam to assess the level of pelvic girdle pain you are having. You will then be fitted with a maternity belt called a sacroiliac joint belt in order to see if this belt can help with your PGP and mobility. You will be asked to wear the belt every day during your daily activities for 4 weeks.

This visit will take about 30 minutes.

Visit 2: Visit 2 will take place 4 weeks after Visit 1. At Visit 2, you will be asked to complete the study questionnaires and have a short physical exam conducted by Dr. Fitzgerald. This visit will take about 15-20 minutes.

RISKS/DISCOMFORTS: The treatment you are assigned to receive may not help. It is possible that the sacroiliac joint belt may cause discomfort and if so, it can be removed. Wearing the belt will not be harmful to your baby.

BENEFITS: We do not know if you will benefit from participating in this study. It is possible that wearing the belt may help with your pelvic girdle pain, but we cannot guarantee this. The information we learn in this study could help other patients in the future.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Some health plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay

for. Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Depending on your health insurance, there may be a co-payment for the standard visits. You will be responsible for any usual out-of-pocket expenses such as co pays, coinsurance or deductibles.

Costs for procedures not included in the standard care will be covered by the research study. If you participate in the study you will receive a free sacroiliac joint belt. You will receive a parking sticker to cover the cost of your parking at Visit 2.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center (LUMC) medical records. The information will be collected by the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; the American Academy of Physical Medicine and Rehabilitation Foundation (AAPM&R), the research sponsor; data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn about how a sacroiliac joint belt may help improve your pain and mobility in pregnancy.

The information we will collect and send includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

We will collect and provide this information about you for as long as you are in the study. Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor, the AAPM&R, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to LUMC and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

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The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Dr. Fitzgerald or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, the AAPM&R, may terminate the study at any time with or without your consent.

Your study doctor may choose to take you out of the study because of unexpected side effects or treatment non-compliance. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-2180.

_____Date:____/_____/____
Signature

Dr. Fitzgerald, the principal investigator for this study, or her associates will be available to answer any questions you may have. Dr. Fitzgerald can be reached at: 708-216-2180.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or Cynthia Tom-Klebba, MA, Director of the Human Research Subjects Protection Program at 708-216-4608.

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Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

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PROJECT TITLE: The Predictive Value of the Active Straight Leg Raise on the Efficacy of a Sacroiliac Joint Belt in Posterior Pelvic Girdle Pain during Pregnancy

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "The Predictive Value of the Active Straight Leg Raise on the Efficacy of a Sacroiliac Joint Belt in Posterior Pelvic Girdle Pain during Pregnancy", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to the AAPM&R as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Colleen Fitzgerald, MD
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153