IRB NUMBER: 205418091813

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 Effect of Ultrasound Guided Posterior Sacroiliac Ligament Corticosteriod Injection In Pregnancy Related Pelvic Girdle Pain: A Randomized Double Blinded Controlled Trial

THE APPROVAL FOR THIS PROJECT EXPIRES ON 09/16/2016.

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.

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 purpose of this study is to see if pelvic girdle pain can be more effectively treated with the use of injectable anti-inflammatory medication (methylprednisolone acetate) plus lidocaine compared with a saline with lidocaine active comparator injection.
This research is sponsored by Scott F. Nadler PASSOR Musculoskeletal Research Grant of the American Academy of Physical Medicine and Rehabilitation Foundation.

Approximately 60 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in the study:

Visit 1: you will sign an informed consent and a copy of the consent form will be given to you. After the consent process you will be given a set of questionnaires to complete, and then will undergo a systematic examination procedures. These procedures will be performed by Dr. Colleen Fitzgerald.

You will be randomized to either the control salt water and lidocaine injection or intervention group; steroid and lidocaine injection in the sacroiliac joint region. Being randomized means that the group you are assigned to is decided by chance like the flipping of a coin. Neither you nor the doctor or study personnel will know which treatment you are assigned to receive. The information may be learned in the event of an emergency.

Control Group is a salt water with lidocaine injection and the

Intervention Group is the ultrasound guided steroid plus lidocaine injection. The medication or salt water with be injected into a single side or both side of the ligament if the pain is in both sacroiliac joint regions.

The study visit is expected to take about 60 minutes to complete.

Visit 2: Will be 4 weeks after injection and you will undergo a physical examination of the external musculoskeletal pelvis and will complete the pain scale, a pain diagram, and questionnaires.

The study visit is expected to take about 30 minutes to complete.

Visit 3: Will be 8 weeks after injection and you will undergo a physical examination of the external musculoskeletal pelvis and will complete the pain scale, a pain diagram, and questionnaires.

Visit 4: Will be 6 weeks postpartum following injection and you will undergo a physical examination of the external musculoskeletal pelvis and will complete the pain scale, a pain diagram, and questionnaires.

The study visit is expected to take about 30 minutes to complete

RISKS/DISCOMFORTS: The treatment you are assigned to receive may not help.

The treatment you are assigned to receive may be associated with more problems or may be less effective than the other treatments in this study that you did not receive.

For the intervention group (steroid injection) expected (common) side effects might include nausea, insomnia, or facial flushing, bleeding, infection, worse pain. Toxicity at high levels and multiple dosing effects are not expected given that this is a low dose of corticosteroids injected locally at the ligament.

Possible rare adverse effects might include severe vomiting or allergic reaction.

Potential risks to the mother as a result of the steroid can affect the hypothalamic-pituitary-adrenal (HPA) axis or how the brain regulates your body's hormones. Changes to this regulatory system in the body only occurs in patient who receive daily or repeated steroid medications for more than 3 weeks. Since this study involves a onetime only dose of the steroid, it is unlikely there will be any effect on this system. Possible though highly unlikely effects could be skin thinning, skin changes, transient swelling or weight gain. More concerning effects on your heart, bones, internal organs and nervous system are not anticipate with this one time only does of steroid.

Potential fetal risks associated with repeat doses may include increase in fetal heart rate, and increase in fetal blood pressure and behavioral changes in the fetus. Typically this effect when if happens goes away in 4-7 days. This potential effect occurs in repeat injections of the steroid medication. In our study there is only one does of steroid medication given so it is unlikely these effects will even occur.

There are no adequate and well-controlled studies in pregnant women on the risk of corticosteroids to the fetus. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits, have yielded an increase incidence of cleft palate in the offspring but in the study you will be participating in methylprednisolone will be administered in the second trimester after the palate is closed.

For the salt water and lidocaine group expected (common) side effects might include bleeding, infection, and worse pain.

There may be unknown risks. You will be notified of any new information that may affect your desire to continue participation in the study.

BENEFITS: We do not know if you will benefit from participation in this research**.**

The information learned from this study may benefit patients in the future.

There is no benefit in this study to the fetus.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital. You can choose to be treated with physical therapy alone and your doctor's usual treatment for your problem.

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

FINANCIAL INFORMATION:
Neither you nor your insurance provider will be billed for any procedures that are performed exclusively for this research study. Those procedures that are being performed for research purposes only include ultrasound & injection.

You will be given a parking sticker for each visit.

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 to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems.

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. The information will be collected by Dr. Colleen Fitzgerald, the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; 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 Pregnancy related PGP "sciatica" can be more effectively treated with the use of injectable anti-inflammatory medication.
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 Loyola University Medical Center or Gottlieb Memorial Hospital (GMH), it may no longer be protected by federal privacy laws.

It is possible that the sponsor, Scott F. Nadler PASSOR Musculoskeletal Research Grant, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to Loyola University Medical Center ("LUMC") or GMH 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/GMH is sending to them.

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/GMH 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/GMH 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/GMH 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/GMH and the sponsor.

For your safety, we may ask that you return to clinic one more time for follow-up. We will also ask that you return any unused study medication. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

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

Your study doctor, the Institutional Review Board, the regulatory authorities, or 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 or serious side effects, treatment non-compliance, or because you are not taking the medication as you were instructed. 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 708-216-2067.

_____ _____

Signature Date

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: 708-216-8078.

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 Elaine Fluder, MSN, Director of the Human Research Subjects Protection Program at 708-216-4608.

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

_____Date:_____

Signature: Witness

PROJECT TITLE:
The Effect of Ultrasound Guided Posterior Sacroiliac Ligament Corticosteriod Injection In Pregnancy Related Pelvic Girdle Pain: A Randomized Double Blinded Controlled Trial

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "The Effect of Ultrasound Guided Posterior Sacroiliac Ligament Corticosteriod Injection In Pregnancy Related Pelvic Girdle Pain: A Randomized Double Blinded Controlled Trial", at Loyola University Medical Center ("LUMC") or Gottlieb Memorial Hospital. I also revoke my consent to release information I provided to LUMC/GMH that allowed LUMC/GMH to use and disclose my medical information to 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:

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