MIDWEST SPINE & BRAIN INSTITUTE RESEARCH INFORMED CONSENT
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Stem cell containing bone graft options and bone morphogenetic protein (BMP) compared to iliac autograft for single level posterior spinal fusion

Investigator: Glenn R. Buttermann, M.D., M.S.

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Investigator: Glenn R. Buttermann, M.D., M.S.

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Introduction

This study is being conducted by Dr. Buttermann at Midwest Spine and Brain Institute. You are invited to participate in this research because you are scheduled to undergo spinal fusion surgery. In order for you to decide whether you want to take part in this study, you should understand the risks and benefits of participation so that you can make an informed decision. This process is known as informed consent. We ask that you read this form carefully and ask any questions that you may have before agreeing to be in this study.

Study Purpose

Successful spinal fusion requires the use of bone graft (to replace missing or damaged bone) and is most reliable using an anterior/posterior technique. This means that surgery is performed from the front (the abdominal area) to fuse the vertebral bodies (thick oval part of the bone that forms the front of the vertebra) and from the back to fuse the facet joints. Facet joints are small joints that are located between and behind vertebrae. The bone graft is placed between the vertebral bodies during the anterior fusion and placed in and next to the facet joints for the posterior fusion. Because there is greater bony surface area between the vertebral bodies, the placement of bone graft in this area usually results in a high fusion success rate.

Bone graft for the posterior fusion may come from a variety of sources. Historically, bone graft is obtained from the iliac portion (curved border) of the patient's own pelvis, but this can result in additional post-surgical pain. Alternative forms of bone graft are available, but we do not know if one alternative is better than another.

The purpose of this research is to determine the ability to achieve a successful posterior spinal fusion using alternative forms of bone graft.

Research Description

This study involves the assessment of alternatives to iliac bone graft during spinal fusion surgery. Four types of bone graft alternatives are being compared to iliac bone graft during the posterior portion of an anterior/posterior one-level lumbar spinal fusion. If you choose to participate in this study, you will be randomized (like a flip of a coin) to receive either your own iliac bone graft, bone morphogenetic protein (BMP, made from proteins found in the human body that stimulate bone growth), or one of the following stem-cell based bone graft alternatives for the posterior portion of your fusion surgery:

- Orthofix Trinity-made from donor bone and bone marrow stem cells
- Allosource Allostem-made from donor bone and fat stem cells
- Nutech Nucel-made from donor bone and placenta (after birth) stem cells

Each bone graft alternatives has been approved by the United States Food and Drug Administration (FDA) and is commercially available with the exception that BMP application is considered "off-label". That is, BMP it is not approved for this indication, it is currently indicated for anterior fusion.

The volume of bone graft that you will receive is the same for each graph type (approximately 5cc).

Approximately 100 patients from the Midwest Spine and Brain Institute are expected to be enrolled in this study. If you choose to take part, your participation will last about 1 year.

Study Procedures

There are no additional surgical procedures required for this study. All patients will receive bone morphogenetic protein for the anterior portion of their fusion surgery. Only the type of bone graft used in your posterior fusion will vary depending on which study group you have been assigned. Subjects will have a 1 in 5 chance of undergoing an iliac bone graft procedure.

At approximately 9 – 15 months after your surgery, you will be asked to return to the Midwest Spine and Brain Institute to undergo a limited CT scan of the fusion level to determine how you are healing. This CT scan will be performed at no cost to you.

Your pain level and functional ability will also be evaluated at this visit.

Risks and Discomforts

All the bone graft options for performing your fusion are already established in clinical practice. All bone graft options have small inherent risks. Use of your own iliac bone may result in pain or pelvic fracture. BMP may rarely result in a seroma (sterile fluid collection due to inflammation). The stem cell alternatives may, vary rarely, result in an allergic reaction or infection. The risks of your spine surgery are reviewed in the "Midwest Spine & Brain Pre-operative Surgery Packet". You will be asked to sign a separate surgery consent form. Less than 2% of patients may not heal both the anterior and posterior portion of the fusion. This may result in pain necessitating a repair surgery (revision fusion).

Assessment of the fusion requires you to undergo a limited CT scan. The radiation from this CT scan is approximately the same as one year of natural background radiation that is found in the earth and air. This amount of radiation is small, but it is in addition to radiation you may receive from other sources.

Benefits

This study will not directly benefit you. The results may be used to help patients in the future.

Alternatives to Participation

The alternative is not to participate in this study. You do not need to take part in this study to receive spinal fusion surgery. If you agree to participate, the type of bone graft you receive will be determined for you by computer randomization.

New Information

It is unlikely that there will be any significant new findings during the study. However, if there are significant new findings that may impact your willingness to continue to participate in the study, this information will be provided to you.

Confidentiality

Your name will not be used in this study. Only your age, sex, spinal levels treated, bone graft type, and surgery outcomes will be recorded. No information that could identify you will be presented or published. Dr. Buttermann and his research staff will be careful to protect your privacy. You do not need to take part in this study to receive spinal fusion surgery or one of the alternative bone graft products. The HealthEast Institutional Review Board (the committee that oversees the rights of people in research studies) and the United States Food and Drug Administration (FDA) may inspect your research records to ensure that the study is being conducted appropriately.

Compensation/Costs

You will not be paid to participate in this study. You are responsible for the cost of your medical care, including your spinal fusion surgery. If you agree to take part in this study, the limited CT scan that is performed approximately 1 year after your surgery will be provided to you at no cost.

Study-Related Injury

In the event that this research results in injury, treatment will be available to you, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, please contact Dr. Buttermann right away at 651-430-3800.

Contacts

Dr. Buttermann can answer any questions you may have about this study. If you have questions or concerns about the study and would like to talk to someone other than the researcher, you may contact Dean Huska, Chair, HealthEast Institutional Review Board at 651-232-3234 or dhuska@healtheast.org.

Voluntary Nature of the Study

Your participation in this study is voluntary. If you refuse to participate in the study, you will not be penalized nor lose any of your health benefits. You may also withdraw from the study at any time, even after giving consent. When the research is complete, you may ask Dr. Buttermann for a copy of any research presentations or publications that have been reported. If you decide not to participate in the study, you will still receive the standard medical care and treatment for your condition.

I have read and understand this informed consent form. All my questions about the study have been answered to my satisfaction. I understand who to contact if I have questions in the future. I willingly give my consent to participate in this study. Upon signing, I will be given a copy of this consent form to keep.

_____ _____

Printed Name of Participant (or Authorized Legal Representative)

_____ _____

Signature of Participant (or Authorized Legal Representative) Date

I confirm that I have personally explained the nature, purpose, duration, and foreseeable benefits and risks of the study to the participant (or if applicable, the participant's legal representative) named above.

_____ _____ _____

Signature of Investigator Date