Double-Blind, Randomized Trial of Peri-operative Subcutaneous Methylnaltrexone Versus Placebo for Postoperative Ileus Prevention after Adult Spinal Arthrodesis

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

NCT03852524

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Study Title:	**Double-Blind, Randomized Trial of Peri-operative Subcutaneous Methylnaltrexone Versus Placebo for Postoperative Ileus Prevention after Adult Spinal Arthrodesis**
Principal Investigator:	**H. Francis Farhadi, MD, PhD**
Sponsor:	**The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Lumbar spinal decompression and fusion is a surgery done to free pinched nerves that cause pain down your leg(s) and to stabilize your spine. Patients undergoing this surgery are at risk of experiencing a complication known as post-operative ileus (POI). This is an obstruction in your normal gastrointestinal (GI) activity that may cause symptoms such as stomach pain, bloating, nausea, vomiting, constipation, difficulty passing gas, and difficulty tolerating a normal diet.

This study is being done to see how safe and effective a drug named methylnaltrexone (given around the time of your surgery) is at preventing this common complication following lumbar spinal fusion surgeries.

You are being asked to participate in this study because you will be having a lumbar fusion procedure and potentially are at risk for experiencing POI.

2. How many people will take part in this study?

It is expected that about 86 patients will take part in this study.

3. What will happen if I take part in this study?

If you agree to take part in this study, you will be randomly assigned (like flipping a coin) to receive either the methylnaltrexone or a placebo (a substance with no effect) within 2 hours before your lumbar spinal fusion procedure and then daily for three days following the procedure. You will receive methylnaltrexone or placebo as a subcutaneous (under the skin) injection. You will not be able to choose which treatment you receive and you will have a 1 in 2 (or 50%) chance of receiving the drug or placebo. Neither you nor your doctor will know which treatment you are receiving until the study is completely finished.

The following procedures are considered standard of care, which means that they would be done even if you were not participating in this study.

Before your surgery, you will have an assessment of your pain. You will also complete a urine pregnancy test if you are able to become pregnant.

After your surgery, you will be watched closely while in the hospital. During this time your ability to use the restroom and your pain levels will be monitored closely. Should your doctor feel you need a computer tomography (CT) scan of your stomach, we will analyze this for the study. You will be monitored for up to 30 days after your surgery for any adverse reactions or complications.

The study team will access your medical records while you are in the study to obtain information about your medical history, demographic information, physical exams, procedures, medications and treatments, and surgery.

4. How long will I be in the study?

You will be in the study for 30 days after your surgery.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Loss of confidentiality:
There is a potential risk to your privacy. Every effort will be made to maintain your privacy, however this cannot be guaranteed.

Risks of Study Drug/Placebo Injection
The risks associated with the injection of methylnaltrexone or placebo include bleeding, pain at the injection site, skin irritation, bruising, fainting, lightheadedness, and infection.

Risks related to the use of Methylnaltrexone:
During the study, you will be monitored for evidence of any side effects. If you develop side effects, your study doctor will give you the care that your need.

1. Gastrointestinal (GI) perforation: cases of gastrointestinal perforation (a harmful opening in your gastrointestinal tract) have been rarely reported in adult patients with opioid induced constipation (constipation that is caused by the use of opioid medications) and advanced illness.
2. Severe or persistent diarrhea: rare cases of severe or persistent diarrhea during treatment have been reported. Your doctor will monitor this very carefully and discontinue therapy with the study drug if you have more than 3 bowel movements per day.
3. Opioid withdrawal: symptoms consistent with opioid withdrawal (side effects that can occur when someone stops taking their opioid medication), including excessive sweating, chills, diarrhea, abdominal pain, anxiety, and yawning have rarely occurred in patients previously treated with Methylnaltrexone.
4. Unknown risks: there may be other risks or side effects that are unknown at this time.

7. What benefits can I expect from being in the study?

You may or may not benefit from participating in this study.

Your participation in this research may help other patients undergoing lumbar spinal fusion procedures in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There will be no cost to you for participating in this study. The costs for your standard of care procedures will be billed to you or your insurance.

The study drug/placebo will be paid for by the study.

10. Will I be paid for taking part in this study?

You will not be paid for participating in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results; and
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. H. Francis Farhadi at 614-366-7784**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Officer
Suite E2140
600 Ackerman Road
Columbus, OH 43202
614-293-4477

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. H. Francis Farhadi at 614-366-7784**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time