Neuraxial Preservative Free Morphine for Normal Spontaneous Vaginal Delivery:
A Prospective Double Blind Randomized Control Trial
PI: Daniel Katz, MD
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STUDY INFORMATION:

Study Title: Does epidural morphine decrease opioid requirements in post-spontaneous vaginal deliveries?

Principal Investigator (Head Researcher): Daniel Katz, MD

Physical Address: 1 Gustave I Levy Place KCC 8th floor New York, NY 10029

Mailing Address: **1 Gustave I Levy Place Box 1010 KCC 8th floor New York, NY 10029**

Phone: 212-241-1518

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to investigate whether or not epidural morphine will decrease opioid use after vaginal deliveries. This is important because decreasing opioid usage may benefit subjects in terms of reducing addiction potential as well as decreasing the frequency of adverse opioid side effects such as changes in breathing or mental status that may accompany these drugs.

Epidural morphine (pain medication injected into the spine) is an opioid that has been used safely in pregnant subjects for cesarean delivery (delivery by operation). In this study, we hope to find if the post-delivery opioid use will decrease after receiving epidural morphine within 1 hour of delivery.

Data currently exists suggesting that epidural morphine may also be used in spontaneous vaginal delivery with good result. However, there is no current **agreement** or gold standard on pain management strategies for spontaneous vaginal deliveries (regular non-operative delivery). There is limited data investigating the use of epidural morphine and its effect on pain and depression after delivery.

If you choose to participate, you will be asked to

1) Deliver your baby at Mount Sinai Medical Center.
2) Going to your normal 6 week post-delivery check up. The data collected will be stored in our internal database. You will not be responsible for bringing any data to your follow up visit. **We will administer a survey at this visit asking you about your mood since your delivery.**
3) Answering a survey about your post-delivery satisfaction scores.

By enrolling in this study, your epidural placement and delivery will be carried out as planned by you and your provider at Mount Sinai. As a member of this study, you will be randomized (assigned by random chance, like the flip of a coin) to receive either:

1. 2.0 mg of preservative free epidural morphine in addition to standard care of an epidural containing bupivacaine 0.0625% and fentanyl 2 mcg/mL during delivery, or
2. standard care (normal Mount Sinai process outside of this research study) (preservative free saline injection with an epidural containing bupivacaine 0.0625% and fentanyl 2 mcg/mL) during delivery. The saline injection is the placebo drug.
3. You will have an equal chance of being given each study treatment. Your anesthesiologist will be given a syringe containing either preservative free saline or morphine and will administer this upon delivery.

There is no cost to you for participating. There will be no compensation involved.

Using morphine in the obstetric population has been previously described to be well-tolerated, with minimal risks, and is considered part of standard protocol for obstetric subjects undergoing cesarean delivery. If used as instructed, the risks are minimal. Like other opioids, morphine can have side effects including nausea, vomiting, constipation, drowsiness, or sweating. These side effects can be treated with medications and are usually minimal. These side effects are no different than any other opioids that are offered with standard of care. The risks of epidural placement are minimal and can include a drop in blood pressure, infection, and bleeding.

Risk of the loss of private information; this risk always exists. However there are procedures in place to minimize this risk.

You may benefit from participation in this research if you are selected to receive the study drug by decreasing your post-delivery pain medication requirements. **You may also have a less-painful post delivery if you are selected to receive the study drug.**

Your participation will help us gain knowledge about the use of epidural morphine and its effect on treating pain after vaginal deliveries.

Instead of participating in this research, you may elect to choose to have the current standard of care. You will not receive an epidural morphine injection if you choose this option.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new

information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are a subject who will be receiving an epidural for a possible spontaneous vaginal delivery.

Funds for conducting this research are provided by The Mount Sinai Hospital

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last expected to last six weeks from your epidural placement.

The number of people expected to take part in this research study at The Mount Sinai Hospital is 300.

DESCRIPTION OF WHAT'S INVOLVED:

If you choose to participate, you will be asked to

1) Deliver your baby at Mount Sinai Medical Center.
2) **Go to your normal 6 week post-delivery** check up. The data collected will be stored in our internal database. You will not be responsible for bringing any data to your follow up visit.
3) Answering a survey about your post-delivery satisfaction scores.

By enrolling in this study, your epidural placement and delivery will be carried out as planned by you and your provider at Mount Sinai. As a member of this study, you will be randomized (assigned by random chance, like the flip of a coin) to receive either:

1. 2.0 mg of preservative free epidural morphine in addition to standard care of an epidural containing bupivacaine 0.0625% and fentanyl 2 mcg/mL during delivery, or
2. Standard care (normal Mount Sinai process outside of this research study) (preservative free saline injection with an epidural containing bupivacaine 0.0625% and fentanyl 2 mcg/mL) during delivery. The saline injection is the placebo drug.

You will have an equal chance of being given each study treatment. Your anesthesiologist will be given a syringe containing either preservative free saline or morphine and will administer this upon delivery. Neither you nor the study doctor will know which experimental study treatment you are getting; however, this information could be obtained in an emergency.

These drugs will be administered at the time of delivery. Afterwards we will monitor your clinical progress until 6 weeks after delivery.

There is no cost to you for participating. There will be no compensation involved.

Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

1) Deliver your baby at Mount Sinai Medical Center.
2) Going to your normal 6 week post-delivery check up. The data collected will be stored in our internal database. You will not be responsible for bringing any data to your follow up visit.
3) Answering a survey about your post-delivery satisfaction scores.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be a decrease of your post-delivery pain medication requirements. You may also have a less-painful delivery if you are selected to receive the study drug.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Using morphine in the pregnant population has been previously described to be well-tolerated, with minimal risks, and is considered part of standard protocol for obstetric subjects undergoing cesarean delivery. If used as instructed, the risks are minimal. Like other opioids, morphine can have side effects including nausea, vomiting, constipation, drowsiness, or sweating. These side effects can be treated with medications and are usually minimal. These side effects are no different than any other opioids that are offered with standard of care. The risks of epidural placement are minimal and can include a drop in blood pressure, infection, and bleeding.

Risk of the loss of private information; this risk always exists. However there are procedures in place to minimize this risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of participating in this research, you may elect to choose to have the current standard of care. You will not receive an epidural morphine injection if you choose this option.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled in the same manner as all other research data. You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your

permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact *Dr. Daniel Katz at 212-241-1518*

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your Name, Address, Telephone number, and dates directly related to you or your baby (birth, admission, discharge, medical record numbers). The researchers will also get information from your medical record at Mount Sinai Medical Center. During the study the researchers will gather information by:

1. Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
2. Reviewing obstetrical records (including current and past prenatal care records, including bloodwork, any hospitalizations at Mount Sinai or other hospital, fetal monitoring results, and ultrasound reports.
3. Reviewing delivery information including gestational age at delivery, opioid use, maternal satisfaction scores, mode of delivery (cesarean section or vaginal delivery), delivery or pregnancy complications, outcome of the baby.

The researchers will also get information from your medical record through our electronic medical record system.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the

list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator)

1. United States Department of Health and Human Services and the Office of Human Research Protection may be interested in the results of this research.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. In records and information disclosed outside of Mount Sinai School of Medicine and Mount Sinai Hospital, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers.

Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still

use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the information in the following box concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time