Ketamine to Improve Recovery After Cesarean Delivery – Part 1 (KINETIC)

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UPMC | University of Pittsburgh Medical Center
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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Ketamine to Improve Recovery After Cesarean Delivery (KINETIC Trial):
PART 1: Lactation Studies

KEY INFORMATION

You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

The purpose of this research is study if low doses of ketamine, a pain killer that is not an opioid, is safe and effective for controlling pain after women have had a c-section birth or who are weaning off of breastfeeding.

In this first part of the study, any of the following groups of women can be enrolled:

- women who are planning not to breastfeed their infants
- women who are withholding breastfeeding during the first 27 hours after birth
- women who are weaning their baby off of breastfeeding.

For the first 24 hours (weaning participants) to 36 hours (c-section participants) after your baby is born or after the scheduled start time, we will collect breast milk, blood, urine, and ask you to do computerized surveys about your pain and mood. You will receive the usual pain medications given to women who have had c-sections, according to your doctor's care, in addition to the ketamine. You will be in the study only while you are in the hospital (c-section participants) or while you are staying in a research unit in Montefiore Hospital called the Clinical Translational Research Center or "CTRC" (weaning participants).

The risks of participating include:

Study Drug: dizziness, lightheadedness, nausea, vomiting, itching, hallucinations, bad dreams, and sleepiness.

Other risks include minor discomforts related to study procedures.

If you are a participant getting a c-section, you may benefit by having better pain control, helping you recover from your c-section. If you decide not to participate in this research, your other choices include getting your usual pain care regimen that your doctor prescribes.

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SOURCE(S) OF SUPPORT:
Clinical and Translational Science Institute (CTSI) Pain Research Challenge

Why is this research being done?

This research is being done to explore a new medication for controlling pain for women who have had cesarean sections. It is part of research to find medications other than opioids to control pain. Opioids are effective pain killers but have negative side effects including addiction.

In this research study, we are testing if ketamine given during and after cesarean sections along with routine care will be transferred into breast milk.

Who is being asked to take part in this research study?
You are being invited to take part in this research study because you are going to have a baby at Magee Women's Hospital, you are having a cesarean delivery, and you are not planning to breastfeed or are willing to withhold breastfeeding for 27 hours after delivery. If you are not having a cesarean delivery, you are being invited to take park in this research study because you are going to be weaning from breastfeeding. Procedures will occur in person and within normal clinical care as much as possible.

What procedures will be performed for research purposes?
If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

<u>Experimental Procedures:</u>
If you qualify and agree to take part in this research study, you will participate in the following things listed below. These procedures will take place electronically, or at Magee Women's Hospital, or UPMC Montefiore CTRC if you are a subject who is weaning.

During your stay at the hospital or CTRC clinic, you will be given a 12-hour infusion of ketamine through your IV. The medicine will start right after your baby is delivered or at the scheduled time in the CTRC clinic. During the infusion, and for 15 hours after the infusion has ended, we will provide you with counseling and support to express samples of your breastmilk. Hand expression and/or breast pumps will be used to express samples. We will help you with these steps. We will enroll 6 women. The results from this study will be used to for a study with many more women.

If you are having a cesarean delivery, after 15 hours, you may nurse your infant but we will do 1 more breast milk collection for the study at 24 hours after the drug infusion ends.

There will be several encounters between you and our study team. In the chart below, where it says ‘Breastmilk’ or ‘Whole blood’, it means those samples will be collected from you. The blood will be drawn from an IV that is in place. Up to 3 mL of blood will be drawn for each of these samples. 24 mL of blood total may be drawn over the course of the study. The study team will assist you in learning how to hand express or use a breast pump to obtain the breast milk sample.

Study Visit	***Where***	***Activity***	***Time***

1	Hospital	Breastmilk - T0-T2 (0-2hrs after infusion start, at earliest opportunity)	15-30 min
2	Hospital	Vital Signs - T0.5 (30min into study drug infusion)	5 min
3	Electronically	Side Effect Diary - T1 (1hr into study drug infusion)	5-10 min
4	Hospital	Vital signs - T1 (60min into study drug infusion)	5 min
5	Hospital	Vital Signs - T2 (2hr into study drug infusion)	5 min
6	Hospital	Vital Signs - T3 (3hr into study drug infusion)	5 min
7	Hospital	Breastmilk - T4 (4 hours)	15-30 min
8	Electronically	Side Effect Diary - T4 (4hr into study drug infusion)	5-10 min
9	Hospital	Vital Signs - T4 (4hr into study drug infusion)	5 min
10	Hospital	Breastmilk - T8 (8 hours)	15-30 min
11	Hospital	Whole blood - T8 (8-10 hours into study drug infusion)	5-10 min
12	Electronically	Side Effect Diary - T8 (8hr into study drug infusion)	5-10 min
13	Hospital	Vital Signs - T8 (8hr into study drug infusion)	5 min
14	Hospital	Breastmilk - T12 (12 hours)	15-30 min
15	Hospital	Whole blood - T12 (12 hours into study drug infusion)	5-10 min
16	Electronically	Side Effect Diary - T12 (12hr into study drug infusion)	5-10 min
17	Hospital	Vital Signs - T12 (12hr into study drug infusion)	5 min
18	Hospital	Whole blood - T12.5 (0.5hr after infusion end)	5-10 min
19	Hospital	Whole blood - T13 (1hr after infusion end)	5-10 min
20	Hospital	Vital Signs - T13 (1hr after infusion end)	5 min
21	Hospital	Breastmilk - T14 (2 hrs after infusion end)	15-30 min
22	Hospital	Whole blood - T14 (2hr after infusion end)	5-10 min
23	Hospital	Vital Signs - T14 (2hr after infusion end)	5 min
24	Hospital	Vital Signs - T15 (3hr after infusion end)	5 min
25	Hospital	Vital Signs – T16 (4hr after infusion end)	5 min
26	Hospital	Breastmilk - T16 (4 hours after infusion end)	15-30 min
27	Hospital	Whole blood - T16 (4 hrs after infusion end)	5-10 min
28	Electronically	Side Effect Diary - T16 (4hr after infusion end)	5-10 min
29	Hospital	Breastmilk - T20 (8 hours after infusion end)	15-30 min
30	Hospital	Whole blood - T20 (8hrs after infusion end)	5-10 min
31	Electronically	Side Effect Diary - T20 (8hr after infusion end)	5-10 min
32	Hospital	Vital Signs – T20 (8hr after infusion end)	5 min
33	Hospital	Urine - T24 (total volume of urine at 24hrs after infusion start)	(passively collected)
34	Electronically	Side Effect Diary - T24 (12hr after infusion end)	5-10 min
35	Hospital	Vital Signs – T24 (12hr after infusion end)	5 min
36 (weaning participants skip this step)	Hospital	Breastmilk - T36 (24 hours after infusion end)	15-30 min

37 (weaning participants skip this step)	Hospital	Whole blood - T36 (24hrs after infusion end)	5-10 min

Your blood, breastmilk and urine samples will be stored in a lab in Magee Women's Hospital and then transferred to a facility in the Pittsburgh Technology Center. It will also be stored in the Montefiore CTRC. They will have anything that identifies you removed. The samples will be analyzed for the amount of ketamine in them. The leftover will be stored frozen for future research use. The results of the analyses will not be shared with you – as they will not affect your clinical care and are for research.

The Side Effect diaries will ask you questions about your mood, stress level, amount of pain you are experiencing.

We will ask you to provide us with your email address and a phone number so that we can keep in touch with you about the study. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

If you are unable to provide an e-mail address, we will contact you by phone.

Your participation in the study would also permit us to re-contact you at a future date for follow-up questions, if necessary.

For the weaning population, a urine pregnancy test will be done before drug infusion or any other study procedures. If you are in the weaning population and have a positive pregnancy test, the PI or Co-I will re-evaluate your eligibly.

What are the possible risks, side effects, and discomforts of this research study?
You will be asked to answer questions regarding your pain and comfort before, during, and after you have your baby. Answering these questions may be viewed as an inconvenience to you.

Risks of Experimental Drug: Some common side effects of ketamine are dizziness, lightheadedness, nausea, vomiting, itching, hallucinations, bad dreams, and sedation. Rarely there can be changes in vital signs, like blood pressure and heart rate. These risks are minimized as much as possible by using doses that are well below the doses that we typically see these side effects. If you are a subject who is weaning and not currently experiencing pain, it is possible though unlikely, that you could experience side effects different from women who take

ketamine who are having pain. The overall risk of side effects with this dose is thought to be low.

Risk of breach of confidentiality: There is a possible risk of a breach of confidentiality. However, we will take all possible steps to prevent this from happening.

Risk of blood draw from existing IV line: There is a low risk of infection from blood draws conducted in the study. However, we will take all possible steps to prevent this from happening.

Risk of Withholding Breastfeeding. Due to potential, yet unknown risks of ketamine exposure through breastmilk, breastfeeding will be withheld for the duration of study drug infusion and for 15 hours after the infusion is stopped. The potential negative implications of withholding breastfeeding over the study period (first 24 hours after delivery) include 1) missed feedings of colostrum (the first milk/substance excreted from the breast after birth, typically 1-4 teaspoons per day) which is high in nutrients, antibodies and white blood cells; and 2) need to assist newborn to transition back to breastfeeding, and 3) possibility for breast discomfort if lactation is stopped. Any participant who withholds breastfeeding, and/or then wishes to breastfeed afterward, will be referred to a lactation consultant for breastfeeding support, to cope with any discomfort if lactation is stopped, and as there are coaxing techniques that can be used to help the newborn make the transition back to the breast.

Risk of answering survey questions. There is a risk that you will be inconvenienced by answering our survey questions. However, we have made sure that our surveys are as brief as possible in order to avoid this risk.

Risk of maternal urine collection. There is a risk that you will be inconvenienced by the study team collecting a sample of your urine. However, we will make this procedure as unobtrusive as possible by using a urine collection hat in your bathroom.

Risk of breastmilk collection. There is a risk that you will be inconvenienced or feel discomfort during collection of breastmilk samples. However, we will minimize this risk as much as possible by allowing you to pump or express breastmilk without the assistance of the study team if you wish, and by having a lactation consultant available to help with obtaining these samples.

Risk of venipuncture with 25g or smaller butterfly needle. If we are unable to get blood draws from an existing IV, we may have to use a 25g or smaller butterfly needle to obtain these samples. There is a risk of infiltration and discomfort, and a small risk of vein inflammation and injury to local structures. However, we will minimize this risk as much as possible by using existing IV's' when possible and relying on trained nursing staff to complete these draws.

What are possible benefits from taking part in this study?

Potential direct benefits of your participation in this study include availability of lactation consultants and keeping the breast pump that we give to you to help you express the breast milk. There are societal benefits in that there will be increased knowledge about whether ketamine administered during cesarean sections is metabolized into breastmilk, and ultimately the results of this study, if significant, will enable health care providers to improve the health of mothers.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). You will be charged, in the standard manner, for any procedures performed for your routine medical care (e.g., the care for pregnancy and delivery at Magee Women's Hospital, and the receipt of labor epidural pain relief).

Will I be paid if I take part in this research study?

You will be paid for the work you perform in this study in the following schedule:

Participant Payment Schedule

Task	Amount	
Breastmilk - T0 (infusion start)	$	62.50
Breastmilk - T4 (4 hours)	$	62.50
Breastmilk - T8 (8 hours)	$	62.50
Breastmilk - T12 (12 hours)	$	62.50
Breastmilk - T14 (2 hrs after infusion end)	$	62.50
Breastmilk - T16 (4 hours after infusion end)	$	62.50
Breastmilk - T20 (8 hours after infusion end)	$	62.50
Breastmilk - T36 (24 hours after infusion end)	$	62.50
Whole blood - T8 (8-10 hours into study drug infusion)	$	62.50
Whole blood - T12 (12 hours into study drug infusion)	$	62.50
Whole blood - T12.5 (0.5hr after infusion end)	$	62.50
Whole blood - T13 (1hr after infusion end)	$	62.50
Whole blood - T14 (2hr after infusion end)	$	62.50
Whole blood - T16 (4 hrs after infusion end)	$	62.50
Whole blood - T20 (8hrs after infusion end)	$	62.50
Whole blood - T36 (24hrs after infusion end)	$	62.50

Urine - T24 (24hrs after infusion start)	$	2.50
Side Effect Diary - T1 (1hr into study drug infusion)	$	62.50
Side Effect Diary - T4 (4hr into study drug infusion)	$	62.50
Side Effect Diary - T8 (8hr into study drug infusion)	$	62.50
Side Effect Diary - T12 (12hr into study drug infusion)	$	62.50
Side Effect Diary - T16 (4hr after infusion end)	$	62.50
Side Effect Diary - T20 (8hr after infusion end)	$	62.50
Side Effect Diary - T24 (12hr after infusion end)	$	62.50
Vital Signs - T0.5 (30min into study drug infusion)	$	4.62
Vital signs - T1 (60min into study drug infusion)	$	4.62
Vital Signs - T2 (2hr into study drug infusion)	$	4.62
Vital Signs - T3 (3hr into study drug infusion)	$	4.62
Vital Signs - T4 (4hr into study drug infusion)	$	4.62
Vital Signs - T8 (8hr into study drug infusion)	$	4.62
Vital Signs - T12 (12hr into study drug infusion)	$	4.62
Vital Signs - T13 (1hr after infusion end)	$	4.61
Vital Signs - T14 (2hr after infusion end)	$	4.61
Vital Signs - T15 (3hr after infusion end)	$	4.61
Vital Signs - T16 (4hr after infusion end)	$	4.61
Vital Signs - T20 (8hr after infusion end)	$	4.61
Vital Sings - T24 (12hr after infusion end)	$	4.61
GRAND TOTAL	**$**	**1,500.00**

You will be paid on a reloadable debit card. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 72% of the expected payment.

Your participation may lead, in the future, to new inventions or products. If the investigators can develop new products from the research use of your survey answers, there are currently no plans to share with you any money or other rewards that may result from the development of these new products.

Compensation for Eligible Referrals:

- You might be eligible to receive additional compensation of $100, if you refer eligible participants to our study team. To receive compensation, the potential other participant you refer to us would need to have been screened by the study team and found eligible to participate. That potential participant may then choose to enroll in our study or may decline enrollment, but you will still receive the $100 compensation if they were

screened as eligible to participate in the study. If you refer a participant that is screened ineligible, you will receive no compensation for this referral.

Who will pay if I am injured because of taking part in this study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial compensation. You waive no legal rights by signing this consent.

Will information be recorded in my medical record?
The medication infusion will be recorded in your medical record as a medication given to you. Medication infusion rates and any adjustments will be recorded in your medication administration record in your medical record. A copy of this consent document will be placed in your paper medical record.

Who can I reach out to with questions about the breastmilk pumping that occurs during this study?
If you have any questions about or issues with lactation following your participation in this research, please reach out to the study team. We will will be available to you for evaluation or counseling at your request, and there will also be a lactation consultant readily available.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet in a secured office at Magee-Womens Hospital, or on secure servers behind the UPMC firewall. Provided e-mail address will be stored in a file within a secure server and will be used strictly for research study purposes. Your identity on these records will be indicated by a case number rather than by your name or other personal identifiers, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. This includes things like your age, health history, medications you are taking, social history and information about your pregnancy and delivery. It will also include information about your labor and delivery, including details and duration of your cesarean section and your pain assessment scores and

medications during your hospital stay. A copy of this consent form and information from the study such as drug dosing, pain control and recovery will be recorded in your medical record.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

Representatives from the Food and Drug Administration and the National Institutes of Health may access research records with your private information for the purpose of monitoring the research and use of study drug.

In the future, the investigators may decide to share data or samples with other investigators both within and outside of this institution. If that were to occur, we would de-identify all of your information prior to sharing data in this way. There are no plans at the present but future research could include genetic or whole genome testing on your samples.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that

requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project. Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project. For projects involving children, records must be maintained for 5 years past age of majority (age 23 per PA State law) after study participation ends.

Can I expect to be automatically advised or referred if any survey results show concerns for me?

There are no questions in Part 1 of this study that would indicate the need for emergency care. Should you, at any time, express any concerns about self-harm or a blue mood, you will be given contact information for Magee Behavioral Health (412-624-2000 option 3) or the Resolve Crisis Line (1-888-796-8226).

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. If you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of your decision to withdraw to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, conditions during your pregnancy or delivery render you ineligible.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study, and I authorize the use of my medical record for the purpose described above. A copy of this consent form will be given to me.

_____

Participant's Signature

_____

Date and time

_____

Participant Name (printed)

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date and time