

Furosemide for Accelerated Recovery of Blood Pressure Postpartum: a randomized controlled trial (FoR BP trial)

A randomized, double-blind, placebo-controlled single center investigation of furosemide's effect on postpartum blood pressure control in pregnancies affected by hypertensive disorders of pregnancy

Consent date: September 13, 2018

NCT#03556761

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Furosemide for Accelerated Recovery of Blood Pressure Postpartum: a randomized controlled trial (FoR BP trial)

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Why am I being asked to volunteer?

You are being invited to participate because you recently delivered a baby and also have high blood pressure. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

About 10% of pregnant women have high blood pressure that affects their pregnancy. Many women have well controlled blood pressures after their baby

delivers (postpartum), however some require more blood pressure medications than others. Furthermore, about 30% of women with high blood pressure in pregnancy need to be seen or readmitted a couple of days after they deliver their baby due to very high blood pressures. To treat these high blood pressures, there are many medications that are breastfeeding friendly.

This study wants to determine the effect of a short course of a common blood pressure medication, furosemide (also known as Lasix), to see if it prevents very high blood pressures after you deliver your baby and if it reduces your chances of being readmitted. If you decide to participate, you will be in one of two groups – in one arm you will be given a low dose of furosemide, in the other you will be given placebo which is an inactive pill with no medication in it (like a sugar pill). These methods are described in more detail later in this form.

We are asking women who are at least 18 years of age and who just delivered at the Hospital of the University of Pennsylvania if they would be interested in volunteering for our research study.

How long will I be in the study? How many other people will be in the study?

You will be involved in the study from delivery of your baby until 10 days after discharge. The study is expected to take approximately 20 months to enroll 385 subjects.

What am I being asked to do?

You are being asked to provide us with some general background personal information, including information on the number and outcomes of previous pregnancies, any medical or gynecologic conditions you have, surgeries you have had, and personal habits of yours.

We will gather information surrounding the outcome of your pregnancy by reviewing your electronic medical record. If you are breastfeeding, we also ask your permission to gather information from your baby's medical record.

You are being asked to allow us to randomly assign you, like flipping a coin, to one of 2 groups after you deliver:

- **Group 1: Furosemide, you will take one 20 mg pill daily for 5 days**
- **Group 2: Placebo (sugar pill), you will take one pill daily for 5 days**

Neither you nor the doctors working on the study will have any control over which group you are assigned to or know which group you are assigned to. In the case of an emergency, your study doctor can find out what medication you received.

The blood pressure medication that we are studying, furosemide, has been used very often at this hospital for blood pressure control after the baby delivers as standard of care. It is safe with breastfeeding, however there are concerns that it

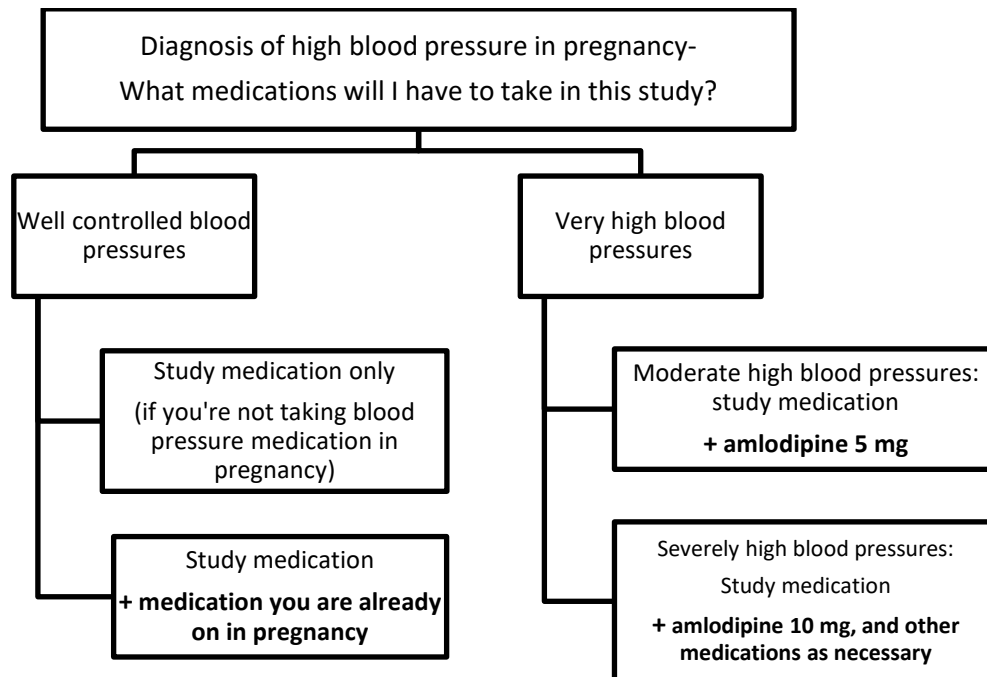
may decrease breastmilk when taken at high doses. We will monitor how you are doing in terms of breastfeeding, and, as per the usual standard of care in our postpartum floor, you will have our lactation consultants available to you at any time. We will be giving you the smallest dose possible to treat your condition in this study.

If your blood pressure is well controlled after your delivery, you will:

- Continue on the same type of blood pressure medication you were already taking while pregnant.
- Receive no additional blood pressure medications (apart from the pill mentioned above).

If your blood pressure is high after delivery, you will:

- Be started on additional blood pressure medications (first line will be amlodipine) as deemed necessary by your doctors that have been proven safe with breastfeeding.
- Your doctors will be instructed to not give you additional diuretic type medications while you are on this study, unless they think it is medically necessary.



Standard of care at our hospital for women with high blood pressures is to check certain lab work to determine the severity of your disease. We will also be looking at these lab values as part of the study as well.

Furosemide can also lower your potassium; therefore, we will be paying attention to your potassium levels (a potassium level is part of your laboratory tests when

you have high blood pressures in pregnancy). If you are noted to have a low potassium, your doctor may give you a potassium supplement.

After discharge from the hospital, we ask that you send in daily blood pressures through our texting program, Heart Safe Motherhood. All women with high blood pressures in pregnancy are enrolled in this program at the Hospital of the University of Pennsylvania. This would be the same level of care you would get even if not enrolled in this study.. To be enrolled in this study, you must also agree to participate in this texting program..

What are the possible risks or discomforts?

Common and Mild:

- dehydration
- dizziness
- nausea/vomiting
- abdominal pain
- diarrhea
- weight loss

Rare and Not Common:

- confusion
- muscle pain/spams
- palpitations
- dry mouth/increased thirst
- weakness
- vertigo, headache, blurred vision
- lab abnormalities
- rash/skin conditions
- Fainting and fatigue due to hypotension (low blood pressure) are possible, but rare, and will be monitored.

Always report any side effect you are experiencing to the study doctor.

As mentioned above, we believe that furosemide is safe for breastfeeding women. However, furosemide can be excreted in breastmilk. In infants that received furosemide, cases of kidney stones were noted, and furosemide has been noted to increase the risk of persistent patent ductus arteriosus in premature infants in the neonatal period. However, this was noted when the medication was given directly to babies; therefore, the doses were much higher than your baby will be exposed to in this study.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible

if such information becomes available. However, based upon the nature of this study, we do not anticipate that this will happen.

What are the possible benefits of the study?

Participation in this study is for research purposes and no health benefit is guaranteed for you. The results of this study could also benefit future patients.

What other choices do I have if I do not participate?

You may choose not to participate in this study without affecting your present or future care at the University of Pennsylvania Health System. Your alternative to providing your consent is to not participate in this study, in which case you would continue to have your blood pressures treated with other medications as deemed necessary by your doctors.

Will I be paid for being in this study?

You will not be paid for being in this study.

Will I have to pay for anything?

You / your insurance will have to pay for any routine medical care that you receive, including all costs related to your delivery and postpartum course. You will not be billed for any medications given for research purposes.

What happens if I am injured from being in the study?

You will receive the same care regardless of whether you participate in the study. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on page 1 of this consent form.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have been recruited and all information has been collected. The study is expected to take 20 months. This study may also be stopped at any time by your physician, the study Sponsor, or the Department of Obstetrics and Gynecology without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study Principal Investigator, or the Department of Obstetrics and Gynecology has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your information will be held in a research database on a password protected computer in a locked office in the Department of Maternal Fetal Medicine. Only the principal investigator or study staff will have access to these files.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from

your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR. Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The following personal health information will be collected and used for research:

- Name, date of birth, medical record number
- Phone number
- Personal medical and obstetric history, general information regarding medical condition of the newborn after delivery
- Information from your and your child's medical records regarding your labor and delivery, and the health of your child.
- Information from a physical examination including cervical exams
- Results of tests and procedures you will undergo during this research study as described in the informed consent form.

Why is my information being used?

Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research to see if the research was done right.

Who may use and share information about me?

The following individuals may use your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

At this time there are no plans to disclose specific information to anyone besides those persons listed above.

Who, outside of UPHS and the School of Medicine, might receive my personal health information?

As part of the study, the Principal Investigator and the study team may review your personal health information, including the results of the research study tests. This information may be disclosed to those listed below upon request:

Individuals or organizations responsible for administering the study:

At this time, there are no plans for anyone besides the researchers involved at the Hospital of the University of Pennsylvania to receive your personal health information.

Regulatory and safety oversight organizations

- University of Pennsylvania Institutional Review Board
- Perelman School of Medicine's Office of Human Research
- The Food and Drug Administration
- The Office of Human Research Protections
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

You have given written authorization to do so

The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place

As permitted by law

Can I change my mind about giving permission for use of my information?

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw

your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

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.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent and HIPAA authorization form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

____ Please initial here if you are willing to be contacted about future research opportunities.