POMPROM: Pitocin or **O**ral **M**isoprostol for **PROM** IOL in Nulliparous Women with Unfavorable Cervical Exams

NCT04028765

Protocol Version 3
Uploaded March 5, 2024
Last updated July 15, 2019
Last approved by IRB 6/22/2023

June 18, 2019

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	POM PROM: Pitocin or Oral Misoprostol for PROM IOL in Nulliparous Women with Unfavorable Cervical Exams
Principal Investigator:	Lisa D. Levine, MD 3400 Spruce Street, 2000 Silverstein Philadelphia, PA 19104 215-662-6913
Co-Investigator:	Whitney Burns, MD 3400 Spruce Street, 2000 Silverstein Philadelphia, PA 19104 215-662-6913
Emergency Contact:	24 hour Labor & Delivery Phone: (215) 662-3815

Summary:
You are being asked to participate in a research study because you are pregnant and your water is broken. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at 215-898-2614 for assistance.

The research study is being conducted to determine if oral misoprostol or oxytocin (Pitocin) helps women whose water is broken before labor deliver faster.

If you agree to participate, you will be randomly assigned to receive either oral misoprostol or oxytocin to induce your labor. You are agreeing to have us collect some background information about you, your labor and delivery process, and

you and your baby's hospital stay after delivery. You will be asked to complete a survey regarding your labor experience during your hospital stay.

Your participation in the study would last through this hospitalization. We will also be collecting information on any hospital or emergency department visits within 1 week after delivery.

There are no direct benefits to you through participation in this study. The most common risk of participation in this study is discomfort related to induction of labor. There are no additional risks to your or your baby from your participation in this study alone.

Should you choose not to participate, you will have an induction of labor with the method of induction chosen at the discretion of your OBGYN.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

What is the purpose of this research study?

About 8% of women need an induction of labor because they break their water before labor begins. A delay in labor can increase the risk of infection and complications for women or their babies. Many methods for inducing/jump starting labor have been studied and shown to be safe and effective for inducing labor but there is no clear answer as to which method leads to a shorter time in labor.

The study will use two commonly used methods and we will see which one leads to a quicker delivery. If you decide to participate, you will be in one of two groups. These two groups are described in more detail later in this form.

We are asking women at the Hospital of the University of Pennsylvania if they would be interested in volunteering for our research study.

Women must be at least 18 years of age and 36 weeks pregnant or greater and having their labor induced because they have broken their water

You are being asked to volunteer so that we can better understand which of these two methods to induce labor will get women delivered faster.

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 today until you deliver your baby. The study is expected to take 24 months to enroll all 155 subjects. All subjects will be from the Hospital of the University of Pennsylvania.

What am I being asked to do?

You are being asked to participate in a study that will look at two different methods of inducing labor to see which has a quicker time to delivery. Both of these methods are used as standard of care methods at our institution and are available to you outside of this study. There are no alterations to these medications for the purpose of this study.

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. Finally, we would like to gather some general information regarding your newborn by reviewing the baby's medical record after you deliver.

You are being asked to allow us to randomly assign you, like rolling dice, to one of two groups for inducing your labor. Neither you nor the doctors working on the study will have any control over which group you are assigned to.

There are many different methods used to induce labor with different methods used by different doctors based on their preference. Having your labor induced can take anywhere from a few hours to a couple of days. In this study, you will have your labor induced with one of the following:

1. Group 1: Oral Misoprostol - This is a pill form of a medicine that you swallow every few hours to soften your cervix, lead to contractions, and begin the labor process.

2. Group 2: Pitocin (oxytocin) – This is an intravenous medication that starts the labor process by causing contractions.

The majority of women will have Pitocin (oxytocin) used during the second half of their labor, no matter what study group you are in to start with.

What are the possible risks or discomforts?

All women will experience some discomfort when having their labor induced, regardless of what method is used. There are risks associated with induction of labor that will be explained to you outside of this form. The study itself involves minimal additional risk or additional discomfort to you and will be the same whether or not you participate in the study. There will not be an increase in the number of exams or the number of blood draws if you participate in the study. The choice of method for inducing your labor will be chosen at random and not by a preference of the physician which is considered a risk.

Induction of labor is already a risk factor for a longer labor compared to women who go into spontaneous labor. We do not believe that this study will increase your risk of this or increase the risk of problems with your baby.

There are NO experimental medications that you would be receiving. Misoprostol is an oral medication that is used for induction of labor. As such, it is associated with a risk of the discomforts of labor; some women may also experience nausea or vomiting. Rarely, women can have too many contractions can occur secondary to receiving this medication. Pitocin is an IV medication that is used for induction or augmentation of labor. As such, it is associated with a risk of the discomforts of labor. Some women may experience too many contractions with this medication as well. Currently, both methods of induction are used by our institution; however, the method received clinically by patients currently depends on the doctor's preference without clear benefits of one method over another. Some things that a physician may consider when making this decision include your cervical exam, whether or not you have had a baby before, and your personal preference.

With any study, there is a small risk of breach of privacy or confidentiality. We do not anticipate this happening and will be taking all possible precaution to keep your and your baby's personal information safe. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

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 will benefit future patients and may benefit you in a future pregnancy.

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 this case, you would continue to have an induction of labor, with one of the methods of induction described above being chosen at the discretion of your doctor. Your doctor may also opt for a different method of induction than those described.

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 induction and your labor and delivery. You will not be billed anything extra for your participation in this study.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for health care. Research results will not be returned to you because they would not be relevant to your health care.

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

Participating in this study does not increase the likelihood of an injury. The same procedures will occur for inducing your labor regardless of whether or not 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 two years. 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.

How will my personal information be protected during the study?

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.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information collected on this study?

After analysis of this data collected in this study, all data will be de-identified. Meaning that while data was collected knowing the identity of the subject, identifiers will be removed and there is no chance for re-identification. Only de-identified data will be used for future research.

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 but will NOT be disclosed during your involvement with this research study:

- Name, date of birth, medical record 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