# Management of the Patent Ductus Arteriosus in Premature Infants Trial (PDA Trial)

**NICHD Neonatal Research Network**

## Informed Consent

## NRN ID number: NICHD-NRN-0059

## NCT03456336

## Revised: April 21, 2022

# APPENDIX D. SAMPLE CONSENT

## *Informed Consent Statement for:*

# PDA Trial

**Investigator**

**Location**

**Telephone**

**Protocol Title**
Management of the Patent Ductus Arteriosus in Premature Infants Trial (PDA Trial)

You are being asked to allow your baby to join a research study because they may have a patent ductus arteriosus (PDA). This is very common in premature babies.

The "ductus arteriosus" connects the main blood vessel that sends blood to the lungs with the blood vessel that sends blood to the body. The ductus arteriosus should close after a baby is born. When it remains open, it is called a "patent ductus arteriosus", or "PDA".

An ultrasound of the heart is used to see a PDA, and how large it is. A PDA is called "*symptomatic"* if the baby is also having breathing problems.

If your baby has not had an ultrasound of the heart, then one will be done to see if your baby has a PDA. Only babies with a PDA will join this study.

Some doctors think every baby with a symptomatic PDA should be treated to prevent future breathing problems (called bronchopulmonary dysplasia, or BPD). This is called active care.

Other doctors think a symptomatic PDA does not cause future breathing problems. These doctors think that the baby only needs to be treated if the PDA is large and the baby is on the breathing machine. This is called expectant care.

In this study, we want to find out if active or expectant care is better. We do not know which way is best.

This study will include babies 22-28 weeks gestational age at birth who have a symptomatic PDA between 48 hours and 21 days of age.

It is important for you to know why this research is being done. It is also important that you understand what will happen in the study and what you are agreeing to. You may talk with family and friends. Please ask questions about anything that is confusing.

This study is sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which is part of the National Institutes of Health (NIH), and is being conducted at 15 sites across the United States. XXXXX <name of site and PI>.

## Why is this study being done?

The purpose of this study is to find out if active or expectant care of a symptomatic PDA is better to reduce breathing problems.

## How many babies will be in this study?

About 836 babies in 15 sites across the United States will be part of this study. XXX babies from XXXX will join in this study.

## What will happen if my baby is in this research?

Your baby will be assigned by chance (like the flip of a coin) to either active or expectant care.

### Active Care

Babies in the active care group will receive one of three common medicines (indomethacin, ibuprofen, or acetaminophen). Your baby's doctor will decide which medicine to use.

If the symptomatic PDA does not close after the medicine, your baby's doctor will decide what other treatment, if any, will be used.

### Expectant Care

A symptomatic PDA can sometimes close on its own without medicine. Babies in the expectant management group will receive medicine only if the symptomatic PDA is large and the baby is on a breathing machine. Your baby's doctor will decide which medicine to use (indomethacin, ibuprofen, or acetaminophen).

If the symptomatic PDA is still large after the medicine your baby's doctor will decide what other treatment, if any, will be used.

### What are other treatments that my doctor might use?

Other treatments may include surgery or cardiac catheterization to close the PDA.

This study will not choose what other treatments to use. You and your baby's doctor will talk and decide if other treatments will be used.

### For Babies in Both Groups

We will collect information from your baby's chart. This information will include your pregnancy and delivery, baby's race and ethnicity, sex, and weight. We will record all treatments for a PDA, infections or surgeries up to about 2 years of age

### Follow-up

We will follow the babies to about 2 years of age so we know how they are doing. This is part of usual care for very premature babies. At this visit, we will weigh and measure your baby. We will ask about your baby's health and any surgeries.

A play test will look at your baby's movement, behavior and development. You will get a report about your baby's development. The follow-up visit takes about 2 hours.

## How long will my baby be in this study?

Your baby will be in this study until he/she comes for the follow-up visit at 2 years of age.

Sometimes more can be learned when study patients are older. We would like to contact you if later follow-up visits are planned.

## What are the possible risks and discomforts from being in this research study?

*All premature babies:* Your baby has been born very early and is at risk for complications of extreme prematurity. This may include serious breathing problems requiring extra oxygen and a ventilator (breathing machine), bleeding inside the spaces of the brain (intraventricular hemorrhage), infections of the intestines (necrotizing enterocolitis), eye problems (retinopathy of prematurity), or developmental problems, including cerebral palsy. Some babies do not survive the complications of extreme prematurity.

*Earlier studies*: There have been smaller PDA studies with groups like active or expectant care done before this study. In those smaller studies, the groups had similar complications of extreme prematurity such as serious breathing problems requiring extra oxygen and a ventilator (breathing machine), bleeding inside the spaces of the brain (intraventricular hemorrhage), infections of the intestines (necrotizing enterocolitis), eye problems (retinopathy of prematurity), and similar rates of survival. In one study, the overall survival was the same but there was lower survival in larger babies in the group like active treatment.

Doctors use both active and expectant care for symptomatic PDA. We don't know which is best.

There may be no benefit to your baby from being part of this study. This study will help us test (Bayley test) done at about two years may find that your child needs additional help.

*This study:* It is possible that babies assigned to one group, when compared to the other group, will have more or less complications of extreme prematurity. These complications may include breathing problems where they may require extra oxygen and a ventilator (breathing machine), infections of the intestines (called necrotizing enterocolitis), eye problems (retinopathy of prematurity) developmental problems including cerebral palsy, or lower survival. This will not be known until the end of the study.

The side effects of medicines used to treat PDA include decreased urine output and bleeding problems. Your baby's feeding may be held when receiving indomethacin, ibuprofen, or acetaminophen which may increase the time he/she needs intravenous nutrition.

The side effects of expectant care are not known.

There may be risks to being in this study that are not known. We will tell you if any new risks are learned while your baby is in this study.

There are no known risks to your baby for the follow-up visit. Your child may become tired during the visit.

## What are the benefits of being in this study?

If your baby is assigned to the expectant care group, the symptomatic PDA may close on its own without treatment. Your baby may avoid side effects of the medicine, and may reach full feedings sooner.

take better care of premature babies in the future. There may be a benefit to you and your child. The benefit is that the developmental

## Will my baby's information be kept private/confidential?

There is a small risk of loss of privacy. Any information about you or your baby will be kept private by law. A study number will be used to identify your baby. Only the local study team will know your baby's name. We will do everything to keep your and your baby's records confidential, but we cannot guarantee absolute confidentiality.

Your or your baby's information may be shared if required by law. Your and your baby's identity will not be given in reports of the study.

This research study has a confidentiality certificate that protects your baby's privacy. If a legal matter happens, researchers may not use anything that might identify your baby without your permission. The researcher may give information to authorities to prevent serious harm to you, your baby, or others.

You may give information to anyone you wish. If an insurer or employer learns that your baby is in a study and you agree to share study data with them, the researcher will do so. This means that you must also guard your baby's information.

Coded study information will be sent to the NICHD Neonatal Research Network's Data Coordinating Center, Research Triangle Institute (RTI) International, in Research Triangle Park, North Carolina. The University Institutional Review Board (IRB), Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) may access these records.

Information from this research study will be kept by <Local Research Institution> and RTI International and may be shared for future research in accordance with the NIH Public Access Policy. The data collected for this study will be analyzed and stored at the Data Coordinating Center, RTI International. After the study is completed, the de-identified, archived data will be transmitted to the NICHD Data and Specimen Hub (DASH), for use by other researchers including those outside of the study. Information released under this policy will not identify your baby or his/her participation in this research study.

A description of this study will be available on ClinicalTrials.gov, ID number NCTxxxxxxx. This website will not include information that can identify you or your baby. At most, the website will include a summary of the results of this study. You can search this website at any time. <Insert Institution-specific HIPAA language, if applicable.>

## What are the costs of being in this research study?

There will be no cost to you or your insurance, for any care that is done as part of this study. The study will pay for all of your baby's care that are done only for the study. All usual care for your baby will be billed to your insurance.

## Will I be paid for being in this research study?

<Insert compensation -or- You will not be paid for your baby's participation in this study.> <Insert if appropriate> The cost of the neonatal follow-up clinic visit will be covered by the study. <Insert if true: If you live more than 50 miles from the follow-up clinic you may be compensated for the cost of travel expenses for the study follow-up visit. We will arrange for an overnight stay at XXXXX (the University Guest House or a comparable facility) for participants living out of state, or at a distance where it is not feasible for return travel in one day.>

## What happens if my baby is injured as a result of being in this research study?

In the event of injury to your baby resulting from their participation in this research, necessary medical treatment will be provided, but any costs for the medical care will be billed to you and/or your insurance company. The <insert name of institution> has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you and your baby do not give up any of your legal rights.

## Is being in this study voluntary?

Yes, being in this study is voluntary. If you decide to let your baby be in this study, you may withdraw for any reason without penalties.

If you do not let your baby be in the study, he/she will still receive all usual care that is available to him/her. The choice of care will be left to you and your doctor. Your choice will not affect the relationship you or your baby have with his/her doctor or other staff, or change the care that your baby receives.

## New Information

We will tell you if any new risks are learned while your baby is in this study.
If you decide to withdraw your baby, your baby receive all usual care for premature babies. If you decide to let your baby stay in the study, you will be asked to sign an updated consent form.

## Right of Investigator to Withdraw Participants

The investigator can withdraw your baby from the study without your approval. Possible reasons for withdrawal include new information that shows the risks of the study are greater than the benefits, or if your baby develops a severe problem that requires the study procedures to be stopped.

## Who should I contact if I have questions or concerns about this study?

If you have any questions about the study or complaints or concerns during the study, you should contact the investigator (Dr. ___), the co-investigators (Drs. ___ or ___) or other study team members via the University Paging Operator: (xxx) xxx-xxxx, the University NICU (xxx-xxx-xxxx or the ____ NICU (xxx) xxx-xxxx, 24 hours a day. If you think your baby may have been injured from being in this study, you can contact the same people.

### Institutional Review Board

Contact the Institutional Review Board (IRB) if you have questions regarding your baby's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the study team. The University IRB may be reached by phone at (xxx) xxx-xxxx or by e-mail at irb@xxxxx.edu.

We are always available to answer your questions. If you have any questions that come up during this study, please be sure to ask us.

# Participants Agreement:

**FUTURE CONTACT**

_____ I AGREE to be contacted for future studies.
Initials

_____ I DO NOT want to be contacted for future studies.
Initials

# STATEMENT OF CONSENT

I confirm that I have read this parental Informed Consent document and have been able to ask questions. I will be given a signed copy of this form to keep.

**I agree to allow my baby to be in this research study <*insert if HIPAA authorization is bundled:* and authorize you to use and disclose health information about my baby for this study>, as you have explained in this document.**

_____
Baby's Name

_____
1st Parent/Guardian's Name

_____ _____
1st Parent/Guardian's Signature Date

_____
Relationship to Baby for 1st Parent/Guardian

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date