Clinicaltrials.gov Document Cover Page

Protocol Title:

BPD Saturation TARgeting (BPD STAR)

Document Date:

10/06/21

NCT Number:

NCT03385330

Document:

Informed consent and HIPAA authorization

Bpd Star Combined Consent Hipaa Authorization

Hello and thank you for taking the time to read this consent. Please read entire form. A member of the research team will be in contact with you to review this form and answer any questions you may have.

If you agree to participate in this study please:

Complete all applicable fields on the signature page Click the "Next Page" button on the bottom on the bottom of the signature pageCheck the "I certify" box and click the "submit"The research team will receive a notification that you signed the consent and will follow-up with you.

Thank you, The BPD STAR Research Team

CHOP IRB Study #17-014522
Effective Date: 10/06/2021
Expiration Date 10/05/2022

INFORMED CONSENT FORM & HIPAA AUTHORIZATION

Study Title: The Bronchopulmonary Dysplasia Saturation TARgeting (BPD STAR) Pilot Trial

Version Date: February 12, 2021

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CHOP IRB#: IRB 17-014522
Effective Date: 10/21/2020
Expiration Date: 10/20/2021

You, and your baby may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to have your baby take part in this study?

You are being asked to take part in this research study because your baby has moderate or severe Bronchopulmonary Dysplasia (BPD). BPD is a chronic lung disease of premature infants. Infants with moderate or severe BPD still need extra oxygen or help with breathing when they reach 36 weeks post-menstrual age (1 month before their due date). Some babies with BPD still need extra oxygen for many months after their due date.

What is the purpose of this research study?

The purpose of this research study is to begin to help doctors learn about the best way to use oxygen to treat BPD in babies like yours. It will help us learn about whether is better to give babies with BPD more or less extra oxygen.

How many people will take part?

About 50 infants will take part in this study

What is involved in the study?

Babies will be randomly placed in either the higher oxygen saturation group or the lower oxygen saturation group. Randomly means that the group is chosen by chance. There is an equal chance of being in either group. The doctors and nurses will adjust your baby's oxygen to keep his or her levels on the monitor in the target range assigned for the study. Some doctors tend to use a higher oxygen saturation target, and some tend to use a lower target. Some doctors use each of the oxygen ranges used in this study. Babies are normally not be held to such a narrow range of oxygen saturations. It is unknown whether staying on the higher or lower end of the range that is usually used is better for infants with BPD.

When your baby goes home we will monitor your child's oxygen levels while they are at home with you. We will give you a monitor that you will attach to your baby's toe every night while he or she is sleeping in the crib. The monitor will send your baby's oxygen information back to the study team at CHOP. This will help us know if your baby's oxygen levels are staying in the target range. If your baby goes home on oxygen, the study will help your doctors decide when your baby is ready to wean off of the oxygen.

How long will you be in this study?

If you agree to take part, your baby's participation will last for about 8 months from the time your baby started the study. There will be up to 3 study visits after leaving the hospital. These visits will be a part of your child's routine care but we will also collect information for the study at those times. At these visits we will get more information on how your baby is doing since he/she left the hospital. We will also contact you to provide an update about your baby's oxygen levels each week as long as he/she is on extra oxygen. We will give you a journal to keep track of certain things that we will ask you about.

What are the study procedures?

The study involves the following research tests and procedures:

Medical record review: We will review medical records throughout the study to collect information about your baby's medical history, conditions, tests and treatments. Test results that are part of their usual care will be reviewed and used for the study. We will also review medical information related to your pregnancy.

Saturation Targeting: Your child will be randomly placed in either the higher oxygen saturation target group or the lower oxygen saturation target group. Your baby's doctors, nurses, and the study team will adjust the amount of extra oxygen given to him/her in order to stay in that target range.

Growth checks: Your child's weight, length, and head circumference will be checked up to 4 times during the study.

Parent questionnaires: You will be asked to do 2 questionnaires - one about how you feel your child is doing and one about how well you feel your child is feeding. These will be done two times during the study. You do not have to answer any questions that make you feel uncomfortable.

Oxygen level monitoring: You will be sent home with an oxygen monitor that your child will wear when he/she goes to bed. The monitor will send your child's oxygen levels to the study team at CHOP. We will monitor your child's oxygen levels, overnight, while he/she is sleeping. At the end of the study, you will bring back the monitor at your final visit.

Oxygen weaning: Your baby's doctor may decide that your baby needs to go home on extra oxygen. This is common in babies with BPD. If your baby has oxygen at home, the study team will help decide when this can be weaned. Your

baby's group assignment in the study may influence how quickly the oxygen is weaned.

Phone follow-up: A member of the study team will call you 1-2 times a month after your baby has been discharged from the hospital to see how he/she is doing. They will ask you questions about your baby's health and how he/she is developing. We may call you more often if your baby is on oxygen and the monitor information suggests that the oxygen flow should be changed.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor. Taking part in a research study involves time but no more risk than is possible in daily life.

Saturation Targeting:

Targeting high oxygen saturations with supplemental oxygen may be associated with increased breathing illnesses, retinopathy of prematurity, and decreased quality of life, without improving neurologic outcomes. Targeting lower oxygen saturation ranges by using less supplemental oxygen may be associated with more episodes of low oxygen levels which might impact growth and development.

Oxygen monitors:

We will give you the sensor with the wrap to attach it your child's foot and make sure it is secure. This is similar to the monitor that your baby wears in the hospital. If your child is uncomfortable, you can reposition the monitor until it is comfortable. The monitor will have an alarm, which will sound if the sensor is not working or if your baby's oxygen level is too low. This alarm can be bothersome to some families.

Growth checks:

There are no known risks associated with checking your child's growth.

Oxygen weaning:

There is no standard approach to weaning of supplemental oxygen in children with BPD. There are no known risks of weaning according to the procedures in this study protocol.

Questionnaires:

The surveys will ask you questions about your child's function and play activities at home and how you feel as a parent. Some of the questions may feel personal to you. You do not have to answer any questions that make you uncomfortable.

Risks of Loss of Confidentiality:

Another risk of the study is the loss of confidentiality or privacy. Every effort will be made to keep your medical record and your child's medical record confidential. There will be no names or other identifiable information about you or your baby in any study report that may be published after the study is complete. Measures taken to protect your and your baby's identity are described in the confidentiality section of this form.

Are there any benefits to taking part in this study?

BPD is diagnosed only in babies who were born early, and we believe that proper oxygen therapy is most likely to impact outcomes if it is started as soon after the diagnosis as possible. Your child might benefit from being in either group in this study. Participants in the higher oxygen saturation ranges may have fewer episodes of hypoxia and improved growth and development. Participants in the lower oxygen saturation ranges may experience less morbidity such as retinopathy of prematurity and fewer respiratory illnesses. We do not know if it is better to use oxygen to keep babies' oxygen levels very high or whether the level should be slightly lower. It is not possible for doctors to monitor your baby's home oxygen levels as closely as we do in this study if you are not in the study. You also may gain more information about your child's progress than you would if you do not join the study. However, we cannot guarantee or promise that your child will receive any direct benefit by participating in this study. The knowledge gained from this research will help health care workers and families make better decisions about oxygen treatment for children with BPD in the future.

Do you need to give your consent in order to participate?

If you decide to allow your child to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study?

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at The Children's Hospital of Philadelphia (CHOP), the Hospital of the University of Pennsylvania (HUP) or Pennsylvania Hospital (PAH).

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

It is possible to stop being part of the oxygen level group that your baby is assigned to, but still continue in the study to receive the follow-up visits, or you could chose to stop all participation. If you withdraw your baby from the study, no new data about your baby will be collected for study purposes. For all infants withdrawn from the study, the information collected about your baby up to the time you withdraw must remain part of the study records.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

Your baby's condition worsens.

The study is stopped.

The study monitor is no longer available.

You cannot meet all the requirements of the study

New information suggests taking part in the study may not be in your best interests.

The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and the study doctor will discuss other options with you. We will tell you about new information that may affect your baby's health, welfare, or willingness to stay in this study.

What choices do you have other than this study?

The alternative for your baby is not to participate in this study. It is a normal practice for babies to receive oxygen therapy in the hospital and at home after discharge. Your choice not to participate would not affect the other medical care. You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about your child will be collected. This will include information from medical records and information that is collected only for this research. We will do our best to keep your personal information private and confidential. However we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your child's identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections; Members of the research team and other authorized staff at CHOP and the University of Pennsylvania and its affiliate hospitals; Representatives of the Thrasher Research Fund, who is the study sponsor funding this research; The study Safety Monitoring Officer. By law, The Children's Hospital of Philadelphia and The University of Pennsylvania and its affiliate hospitals are required to protect your child's health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP and The University of Pennsylvania and its affiliate hospitals to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

We will do everything we can to keep others from learning about your infant's participation in this study. If a legal matter happens, researchers may not use any information that might identify your child unless you give your okay. You may give information about your child or this study. If an insurer or employer learns that your child 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 child's private information. The researcher may give information to authorities to prevent serious harm to you, your child, or others.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Sara B. DeMauro
The Children's Hospital of Philadelphia
Division of Neonatology
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Safety Monitor, who is an expert not directly involved in this study, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your child's health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care - procedures, medications and doctor visits - will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

Parents/participants will be reimbursed up to $300 ($50 per month, up to 6 months) for their time, travel and parking after each visit. Participants will also receive a BPD Star Tote at discharge to help carry the study equipment.

If you receive payment using a bankcard, the bank will have access to your name, address and phone number.

We may share your child's data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You and your child will not receive any financial benefit from research done on data.

Who is funding this research study?

The Thrasher Research Fund is providing financial support for this study and all of the research procedures mentioned earlier on this form. Masimo, Inc. is providing the oximeters we will use in this study but they will not provide any other money and will not have access to the study data. Please ask Dr. DeMauro if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. DeMauro at 267-426-4976. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and The University of Pennsylvania and its affiliate hospitals approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the CHOP IRB Office at 215-590-2830 or the University of Pennsylvania IRB Office (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.

What happens if your baby is injured during the study?

If your baby is hurt or gets sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think your baby has been injured from taking part in this study, call Dr. DeMauro at 267-426-4976. She can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

Consent for Use of Data for Future Research

As part of the study, we will collect information on your child's motor and cognitive ability, the parent questionnaire, and monitoring your child's oxygen levels. We may wish to use the information in a future study about how children with BPD respond to different oxygen saturation levels. The information and sample will be given a unique code and will not include information that can identify your child.

Information that can identify your child may be kept permanently in a computer database at CHOP. Only the study team and those working with them on this study will be able to see information that can identify your child. If you leave the study, you can ask to have the data collected about your child removed. You can also ask us to remove information that identifies your child from the data.

Please indicate whether you will allow your child's data to be used for future research:

(Select one of the following choices)

◯ My child's study data may be used for other future research studies. If the data are shared outside of CHOP, no identifiable information will be included.
◯ My child's study data may be used for this study only.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your baby take part in this research study and you are legally authorized to consent to your baby's participation. You are also agreeing to let The Children's Hospital of Philadelphia use and share your and your baby's health information as explained above. If you don't agree to the collection, use and sharing of the health information, you and your baby cannot participate in this study. NOTE: A foster parent is not legally authorized to consent for a foster child's participation.

Do you consent for your baby to participate in this study?

◯ Yes
◯ No

Consent for Child's Participation

Name of Child Subject

_____
(Your baby's first and last name)

Name of Authorized Representative

_____
(Parent or Gaurdians first and last name)

Relation to subject:

◯ Parent
◯ Legal Guardian
(Select one)

Authorized Subject Representative Signature

_____

Date and time

_____

Consent for Parents' participation

Name of Parent or Legal Guardian

_____
(Your full name)

Relationship to the subject

◯ Mother
◯ Father
◯ Legal Guardian

Signature of Parent or Legal Guardian

_____

Date

_____

Name of Parent or Legal Guardian

_____
(Your full name)

Relationship to the subject

◯ Mother
◯ Father
◯ Legal Guardian

Signature of Parent or Legal Guardian

_____

Date

_____