

## Why is this study important?

- Your baby has a lung disease called bronchopulmonary dysplasia (BPD) and could develop pulmonary hypertension, which could worsen the lung disease. There are no medicines to prevent pulmonary hypertension. It's important to find new ways to prevent long-term lung problems in babies with BPD, because babies with BPD and pulmonary hypertension have a higher risk of dying or having a longer stay in the hospital, which could lead to other complications, such as infection.
- Through this study, we will learn more about the safety of a drug called Sildenafil, whether it can help prevent pulmonary hypertension, and what doses are best for use in premature babies with BPD.
- You do not have to allow your baby to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time.

*Thank you for considering participation in the Sildi-Safe study.*



To learn more about the  
**Sildi-Safe** study,  
please contact:

**Research Coordinator(s)**

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Or view our online video at:

<https://youtu.be/Kekk9NkM1mU>



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*A research study to test  
the safety of Sildenafil in  
premature infants with severe  
Bronchopulmonary Dysplasia*



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**Institutional Review Board**



## What is the study about?

Sildi-Safe is a research study being done to test the safety of a drug called sildenafil in premature infants with BPD. We want to see if sildenafil can help prevent pulmonary hypertension, which can worsen lung disease in these babies.

## What medicine will my baby take?

If you join, your baby will receive either sildenafil or placebo (a liquid with no drug in it). Treatment will be assigned at random (like rolling dice). Your baby will have about a 75% chance of receiving the active drug. The drug or placebo will be given 3 times a day for up to 32 days either through a tube in your baby's vein, by mouth or through a feeding tube, if they have one. Sildenafil or placebo will be given in addition to any other medications your baby's doctor thinks are needed.

## What else will happen?

We will record information throughout the study, such as the time and the amount of study drug your baby receives, blood pressures, weights, and breathing status. We will also record what medicines your baby is taking since the start of the study and review other tests, like labs and heart procedure reports (echocardiogram, heart catheterization) that have been ordered by your baby's doctor. We will check for any changes in your baby's medical condition or any problems your baby may be having.

There will also be up to 8 blood draws, totaling about 1½ teaspoons, to measure how well the body processes and eliminates the study drug or placebo. We will do our best to time the blood draws to be at the same time when your baby is having blood taken for other reasons.

We will continue to record information about your baby's health for up to 28 days after the medication dosing is finished.

## Why should I join?

It is possible that babies with BPD who get sildenafil will have improved breathing and a lower risk for pulmonary hypertension; it is also possible that there will be no benefit. We hope the information that we learn from this study will help us to take care of premature babies like yours in the future.

Ask your study team if there is any compensation or other resources available to you for your participation in this study (e.g., a stipend or reimbursement of expenses).

## Who can join?

Your baby may be able to join the study if they are less than 29 weeks gestational age at birth and has severe BPD.

Please talk with your health care provider and loved ones to see if Sildi-Safe is a good fit for you and your baby.

## Where can I join?

If you are interested in participating or have questions, please contact our research coordinator:

**Anne Holmes**

**816-983-6378**

**[aholmes@cmh.edu](mailto:aholmes@cmh.edu)**



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