

Thank you for considering our study!



The study is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the Department of Health and Human Services.



Who is Participating?

University of Alabama at Birmingham ▪ Brown University ▪ Case Western Reserve University ▪ University of Cincinnati ▪ **Duke University** ▪ Emory University ▪ University of Iowa ▪ University of New Mexico ▪ University of Pennsylvania ▪ Research Institute at Nationwide Children's Hospital ▪ University of Rochester, New York ▪ University at Buffalo, New York ▪ Stanford University ▪ University of Texas – Southwestern ▪ University of Texas – Houston ▪ University of Utah ▪

For more information on the NICHD Neonatal Research Network, visit: <http://neonatal.rfi.org>.



NICHD Neonatal Research Network

Milrinone in Congenital Diaphragmatic Hernia



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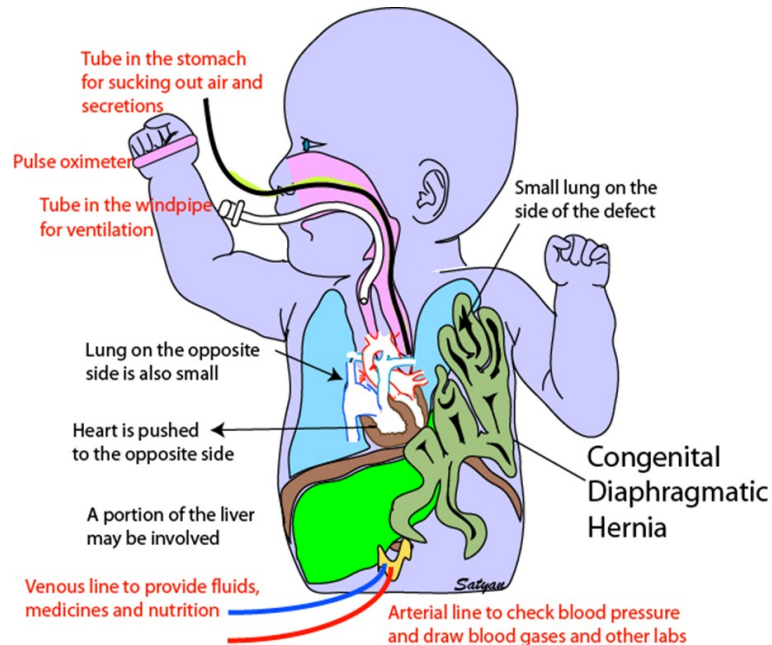
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What is Congenital Diaphragmatic Hernia?

Congenital Diaphragmatic Hernia (CDH) is a birth defect where there is a hole in the muscle that helps you breathe, called the diaphragm. The hole is either on the left or the right side but more commonly the left.

The contents of the belly, including the stomach, spleen, liver, and intestines go up into the chest through the hole in the muscle. There is little room in the chest to allow the lungs to grow and develop.



What is the purpose of this study?

Congenital diaphragmatic hernia results in a smaller lung size which may lead to high blood pressure in the lungs and low blood flow to the lungs. Infants with CDH require ventilation through a breathing machine with high levels of oxygen. The purpose of this study is to find out whether a drug called Milrinone, when given to infants with CDH, will help by opening up the blood vessels in the lung which may help the heart and lungs give enough oxygen to tissues and other organs. If your baby's oxygen level cannot be maintained by the breathing machine, he/she may need to be placed on heart-lung bypass also known as extracorporeal membrane oxygenation (ECMO). We hope to gather data on whether or not the use of Milrinone decreases the need for ECMO.

What treatment will my baby receive if they participate in this study?

Your baby will receive an intravenous (IV) infusion of Milrinone or placebo (sugar solution). A placebo is a pill, liquid or powder that has no active medicine in it. If you decided to allow your baby take part in this study, he/she will be randomly assigned (like a flip of the coin) to receive either Milrinone, or placebo. Neither the treating neonatologist or the study coordinators will be aware of whether your baby will be receiving Milrinone or the placebo.

How is Congenital Diaphragmatic Hernia typically treated?

CDH can be treated in a number of ways. Initially, babies are supported on a breathing machine with oxygen. Babies with CDH require surgery to repair the hole in the diaphragm and to move the organs into their proper places. This surgery is typically performed when the baby is relatively stable with adequate blood flow to the lungs.

Will the study help my baby?

There may be no direct benefit to your baby from participating in this study. We believe that administration of milrinone may improve oxygen levels and benefit your baby. It is our hope that the information gained from this study will help in the treatment of future babies born with CDH.

Are there any risks to being in the study?

Infants with CDH represent a high-risk population with mortality ranging from 30 to 40%. Additional risks from the use of IV Milrinone include a drop in blood pressure, heart rhythm problems (reported in adults) and intracranial hemorrhage (reported in critically ill newborn infants without CDH).

What treatment will my baby receive if I do not consent to this study?

If you chose not to participate in the study, your baby will receive the treatment that is the standard of care in your hospital. It is possible your baby will still receive Milrinone as part of regular clinical care. Since hospitals vary in their standard of care, you should discuss the treatment plan with your baby's doctor.

What is expected once my baby is discharged?

As part of this study, you will be asked to participate in phone surveys once your baby is 4, 8, and 12 months old. We will contact you to complete the follow-up questionnaires about your baby's health.

Does my baby have to take part in this study?

No, your baby does not. You may tell the researcher "no" if you do not want your baby to be in the study.