

# Evaluation of a Medication to Prevent Pulmonary Hypertension in Children Undergoing Open Heart Surgery

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## **What is the purpose of the study?**

The purpose of this study is to evaluate a medication called Citrulline in children who have open heart surgery. Children who have heart surgery are at risk for *pulmonary hypertension*- a condition where the blood pressure in the blood vessels in the lungs is dangerously high. Citrulline is an amino acid normally made in the body and is present in many fruits and vegetables that we eat. The purpose of this study is to see if Citrulline is safe and effective in preventing or minimizing pulmonary hypertension after open heart surgery.

## **Who is eligible to participate in the study?**

Children who are undergoing open heart surgery for 1 of 5 specific surgical procedures: AV Canal repair, VSD repair, Bidirectional Glenn, Modified Fontan and Arterial Switch.

## **What does the study involve?**

Children who participate in this study will be randomly assigned (like flipping a coin) to receive either Citrulline or a placebo (a non-medicinal comparison agent) over a period of 48 hours. They will also have urine and blood samples (1 ½ tablespoons total) at 7 time points during the study. The blood draws will not involve an additional needle stick as they will be taken from their existing central line.

## **What are the benefits?**

There is no guarantee of benefit by participating in this study. This study will provide important information on the safety of Citrulline in children undergoing open heart surgery and whether it can prevent pulmonary hypertension.

## **What are the risks?**

As with all drugs, there are possible side effects. The research study team will discuss all risks with interested participants prior to enrolling in the study.

## **Is there any compensation for participating?**

There is no compensation for participation in this study.

## **How will I get more information about the study?**

Interested parents will discuss the study with a member of the research team and will be given a parent permission / consent form that further explains all of the details of the study. Study procedures will not be started until the parent(s) fully understands what is involved in the study and has signed a parent permission/ consent form.

**Status:** Recruiting

**Site(s):** Advocate Hope Children's Hospital, The Heart Institute for Children

## **Who should I contact for more information?**

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