

FUEL

The Fontan Udenafil Exercise Longitudinal Trial

The Purpose of the Study

The Fontan operation has been a wonderful success for children born with single ventricle congenital heart disease, yet it is not a cure. Within decades after the Fontan operation, individuals can experience a decline in heart & breathing function, liver problems, and ultimately heart failure. It is important that we find ways to prevent these declines and Udenafil might be a useful medication.

What is Udenafil?

Udenafil is a medicine that helps relax blood vessels and improve blood flow to the lung, which is especially important after the Fontan operation. Everything that we know so far about Udenafil suggests that it is safe. Some children get mild and temporary symptoms such as headaches, an upset stomach, flushing of their cheeks, and nasal congestion.

Studies in teenagers taking Udenafil do not show an increase in spontaneous or persistent erections. We encourage you to speak with your provider about any concerns you may have regarding this and all of the above noted symptoms.

What is involved in the FUEL trial?

Qualifying participants who are ages 12 to less than 19 will:

- Visit a participating heart center 4 times over 6 months.
- Have two blood draws, an echocardiogram, an exercise test and a test to measure how well the blood vessels work at the first and last visit (8-9 hours per visit).
- Have blood pressure and heart rate checked the 2nd week and 3rd month. These visits can be as short as 30 minutes each.
- Be randomly assigned to take Udenafil or a sugar pill. The pills will look the same and neither the study team nor families will know which the participant is receiving. In the rare case of medical need, the study team can find out which type of medication is being given.
- Be invited to participate in one-year "Open Label Extension Trial" after the final 6-month FUEL study visit. All participants will receive Udenafil during this phase.
- Receive an iPod Touch to keep track of medication and visit schedules, and some reimbursement for time and travel.

“ I like helping with the research studies because it's really cool to be a part of advancements in the medical world in a way not many other people can. It almost gives a purpose to having a heart defect. ”

ERIN, AGE 16
FUEL PARTICIPANT



Find out more about how you can help

Participating in the FUEL Trial may improve the lives of children with single ventricle congenital heart disease. Getting the information to make a good decision is important, so:

Ask your child's pediatric cardiologist or nurse practitioner for more information or advice about joining.

For more details about the study, go to the FUEL Trial study website:
www.PediatricHeartNetwork.org/Studies/CurrentStudies/FUeLandFUeLOLE

For specific details about eligibility and to find a center near you, go to:

www.clinicaltrials.gov/ct2/show/NCT02741115

Additional centers are occasionally added. Call the coordinator or doctor to get your questions answered.