

OTHER FACTORS TO CONSIDER

A group of doctors, nurses, and other medical staff (the study team) will:

- explain the possible risks and benefits of the study
- monitor your child's health carefully
- provide your child with the study medication and study-related tests, at no cost to you.



You and your child will not be paid to take part in this study. You may be reimbursed for reasonable time and travel costs.

Study participation is completely voluntary. If you decide you want your child to take part and then want to leave, you can do so at any point. You do not need to give a reason for leaving.

WHO CAN TAKE PART?

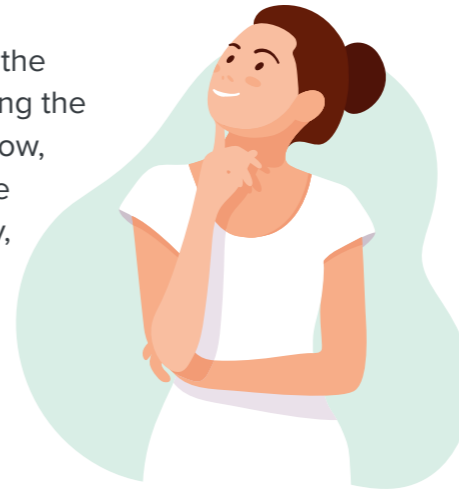
To take part, your child must:

- be 12–18 years of age
- have had the Fontan procedure
- currently be taking antiplatelet or anticoagulant therapy.



HOW DO I GET MORE INFORMATION?

Please contact the study team, using the information below, to find out more about the study, or if you have any questions or concerns.



CONTACT INFORMATION

Dara Watkins
Clinical Trials Coordinator
fuel2@cmh.edu
816-302-3633

PATIENT INFORMATION



Learn more about the FUEL-2 Study

A study for teenagers 12–18 years of age with single ventricle heart disease (SVHD) who had the Fontan procedure.



ABOUT THE FUEL-2 STUDY

This clinical research study is looking at how safe a new investigational medication is and whether it can help teenagers with SVHD who had the Fontan procedure.



400

More than 400 teenagers will take part in this study at study centers around the world

A clinical research study is a medical study that tests medications before they can be given to patients. Sometimes medicines affect children and teenagers differently from the way they affect adults. We need to know if a medication is safe and works, as well as what side effects may be seen when it is given to young people.

WHY IS THIS STUDY IMPORTANT?

People with SVHD need to have multiple surgeries to help their heart work better. One of those surgeries is called the Fontan procedure, which is done to direct the blood to the lungs instead of the heart.

However, the Fontan procedure affects the way the heart pumps blood around the body, and lowers the ability to exercise and carry on with daily activities. There are medications to help improve blood flow in people with SVHD, but there are few options that work for younger patients.

The investigational medication being studied in the FUEL-2 Study works by lowering the pressure in the heart's blood vessels and helping the heart pump blood around the body. It is hoped that the investigational medication will help teenagers who had the Fontan procedure to have more energy during their day-to-day activities.

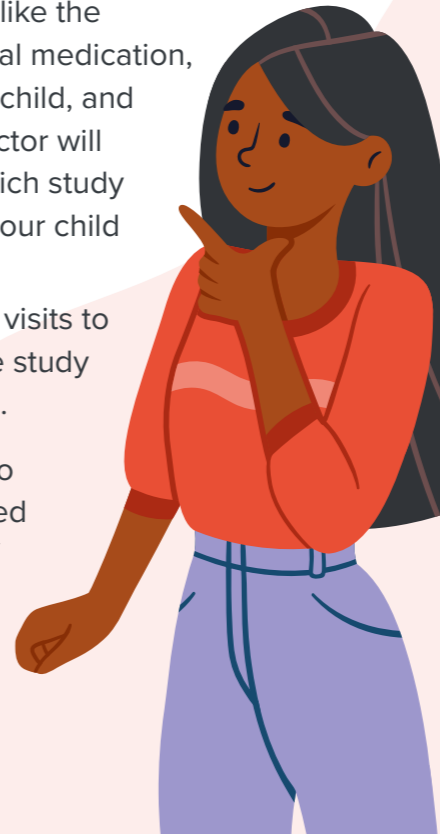


WHAT DOES THE STUDY INVOLVE?

If you agree to have your child join the study, they will be in the FUEL-2 Study for up to 7 months. During this period, your child will:

- receive either the investigational medication or a placebo (together referred to as the “study medication”). The placebo will look just like the investigational medication, so you, your child, and the study doctor will not know which study medication your child is taking
- have up to 2 visits to complete the study assessments.

You will need to sign an Informed Consent Form/ Assent Form before any assessments are done.



THE STUDY IS MADE UP OF 3 PARTS



Screening period (1 day)

Once you and your child sign the consent/assent forms, you will visit the study center to see if the study is right for your child.



Study treatment period (about 6 months)

- Your child will take the study medication by mouth, twice a day, every day.
- You and your child will have regular telephone calls with the study team to check on your child's health.
- At the end of this period, you and your child will visit the study center one more time to complete the study assessments.



Follow-up period (about 1 month)

The study team will call you and your child once to check on your child's health after they have finished taking the study medication.