

# SHAPE of Portal Hypertension in Children

NCT04720456

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Status	RECRUITING
Phase	Phase 2
Sponsor	Thomas Jefferson University
Enrollment	120 participants

## Plain Language Summary

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This study uses a specialized ultrasound with a contrast agent to measure blood pressure in the portal vein (a major vein carrying blood to the liver) in children with liver disease. High pressure in this vein — called portal hypertension — is a serious complication of chronic liver disease.

**\*\*You may be eligible if:\*\***

- You are a child with chronic liver disease, with or without portal hypertension

**\*\*You may NOT be eligible if:\*\***

- You are pregnant
- You have a known allergy to eggs or egg-based products (the contrast agent contains egg components)
- You have had a prior liver transplant
- You have cystic fibrosis, chronic lung disease, or significant heart disease
- You have a clot or blockage in the portal vein
- You have a syndrome involving missing or extra spleens (asplenia/polysplenia) with biliary atresia

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

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### Inclusion (2)

- Patients with a diagnosis of chronic liver disease without portal hypertension.
- Patients with a diagnosis of chronic liver disease with portal hypertension.

### Exclusion (12)

- Subjects who are pregnant.
- Patients with known or suspected hypersensitivity to egg phosphatidyl serine or with a history of anaphylactic allergy to eggs or egg products.
- Subjects with allergy to egg products or other components of the ultrasound contrast agents will be excluded.
- History of allergic reaction to Lumason®, sulfur hexafluoride, sulfur hexafluoride lipid microsphere components, or other ingredients in Lumason (polyethylene glycol, distearoylphosphatidylcholine (DSPC), dipalmitoylphosphatidylglycerol sodium (DPPG-Na), palmitic acid)
- History of allergic reaction to Sonazoid
- ... and 7 more (see full listing online)

## Locations (1 total)

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The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States

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<https://clinicaltrials.gov/study/NCT04720456>

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