

Intraoperative Contrast-Enhanced Ultrasound Evaluation of Blood Flow at the Time of Surgical Hip Reduction for DDH

NCT03107520

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Children's Hospital of Philadelphia
Enrollment	125 participants

Key Eligibility Criteria

Inclusion (4)

- Males or females between 4 months and up to and including 24 months of age at the time of surgery.
- Diagnosed with DDH.
- Failed conservative treatment, or present with late-diagnosed DDH (where conservative treatment would not be appropriate to initiate at their age), and are undergoing closed or open reduction and spica casting.
- Informed consent (parental permission)

Exclusion (5)

- > 24 months of age at the time of surgery.
- Subjects with DDH who are successfully treated with conservative measures and do not require surgical reduction.
- Previous open hip reduction of the affected side
- Children with known complex congenital heart disease or unstable cardiopulmonary conditions (as noted in the package labeling for Lumason) including acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure or serious ventricular arrhythmias 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-Ns), palmitic acid). Parental/guardian permission (informed consent) and if appropriate, child assent.

Locations (1 total)

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