

# PHIL® Embolic System Pediatric IDE

NCT03731000

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Alejandro Berenstein
<b>Enrollment</b>	15 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Subject is <22 years of age
- Subject and legally authorized representative are willing and capable of complying with all study protocol requirements, including specified follow-up period.
- Subject's legally authorized representative(s) must sign and date an IRB approved written informed consent prior to initiation of any study procedure
- Subject has an intracranial dAVF that is deemed appropriate for embolization with PHIL without significantly increased risk to collateral or adjacent territories, OR subject has been previously treated with other embolic materials for dAVF.

### Exclusion (14)

- Subject presents with an intracranial mass or is currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region
- Subject has known allergies to DMSO (dimethyl sulfoxide), iodine or heparin.
- Subject with a history of life threatening allergy to contrast media (unless treatment for allergy is tolerated).
- Female subject is currently pregnant.
- Subject has an acute or chronic life-threatening illness other than the neurological disease to be treated in this study including but not limited to any malignancy or debilitating autoimmune disease

... and 9 more (see full listing online)

## Locations (1 total)

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Mount Sinai Hospital, New York, New York, United States