

# Study of an Intrathecal Port and Catheter System for Subjects With Spinal Muscular Atrophy

NCT05866419

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Alcyone Therapeutics, Inc
Enrollment	90 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Subject is 3 years or older
- Subject diagnosed with SMA who are candidates for Spinraza treatment as indicated in its label
- Subject resistant to lumbar puncture (LP), where resistance is defined as:
- Subject with respiratory issues or other comorbidities who is at an increased risk for complications due to the need for repeat anesthesia and imaging radiation exposure to safely perform LP; or
- Subjects for whom the treating physician determines implantation of the ThecaFlex DRx™ System is otherwise in the subject's best interest

... and 4 more (see full listing online)

### Exclusion (21)

- Subject meets any of the contraindications for use of the ThecaFlex DRx™ System as outlined in the ThecaFlex DRx™ System Instructions for Use
- Presence or history of (< 6 months prior to the procedure): an implanted microinfusion pump, intrathecal catheter, or other intrathecal drug delivery devices/component, or implanted shunt for drainage of cerebrospinal fluid (CSF), or reservoir in the CSF space (note: any ThecaFlex Port and Catheter System must not be placed in the same location as a previous indwelling port and catheter)
- Subject is pregnant or nursing or plans to become pregnant during the course of the clinical investigation
- Any condition or event, which in the opinion of the Investigator may adversely affect the safety and effective implantation and use of the ThecaFlex DRx™ system or confound the clinical investigation, including:
- Severe structural impediment that may preclude safe implantation of the catheter and port

... and 16 more (see full listing online)

## Locations (21 total)

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Barrow Neurological Institute, Phoenix, Arizona, United States  
Children's Hospital Orange County, Orange, California, United States  
Stanford Medical Center, Palo Alto, California, United States

... and 18 more locations

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<https://clinicaltrials.gov/study/NCT05866419>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.