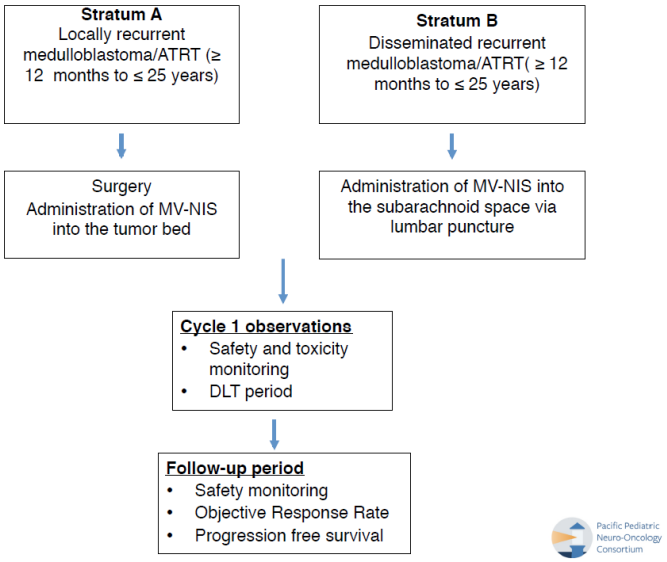
RESEARCH PROGRESS REPORT – January 2019

Modified Measles Virus (MV-NIS) for Recurrent Medulloblastoma or AT/RT			
Official Protocol Title	A Phase 1 Study of Modified Measles Virus (MV-NIS) for the Treatment of Children and Young Adults With Recurrent Medulloblastoma or Recurrent Atypical Teratoid Rhabdoid Tumors (AT/RT)		
Institution	University of California, San Francisco; Pacific Pediatric Neuro-Oncology Consortium (9 sites)		
Principal Investigator	Sabine Mueller, MD, PhD, MAS		
Type of Study	Phase I	**Type of Cancer**	CNS
Number of Patients Enrolled to-date	16	**NIH Trial Listing**	NCT02962167 https://clinicaltrials.gov/ct2/show/NCT02962167
Target Accrual	24	**Date Opened**	Nov 2016

Objective

This is a two arm Phase I study within the Pacific Pediatric Neuro-Oncology Consortium (PNOC). This study will look to determine the safety and recommended phase 2 dose of the modified measles virus (MV-NIS) in children and young adults with recurrent medulloblastoma or atypical teratoid rhabdoid tumor (AT/RT).

Trial Description



This is an open label, multi-center, Phase I study to assess the safety of administering MV-NIS directly into the tumor bed (for locally recurrent medulloblastoma or ATRT patients) or into the subarachnoid space (for disseminated recurrent medulloblastoma or ATRT patients).

For locally recurrent patients, MV-NIS will be directly administered into the tumor bed following a standard of care surgical resection. For patients with disseminated recurrence, MV-NIS will be injected via lumbar puncture (LP). This is a one-time administration for either locally or disseminated recurrence.

Patients will be closely monitored for 30 days after injection, and then followed for evaluation of 6 month progressive free survival and overall response rate.

Enrollment Status

The study is going well. As expected, accrual in Stratum A (focal disease recurrence) is slower. Dr. Mueller is working on the FDA submission to allow for a repeat administration of MV NIS.

PNOC005 - *Treatment of Recurrent Medulloblastoma/ATRT with Recombinant Measles Virus*

Total enrollment to date:

	Dose Level 1	Dose Level 2	Dose Level 3
Stratum A	3/3	2/3	0/6
Stratum B	3/3	3/3	5/6

Open sites:

- UCSF, Seattle, Lurie, CHOP, WUSTL, DFCI, CHLA, Nationwide

Updates:

- In discussion with Vyriad (who now licensed the MV NIS) we plan to amend the protocol to offer D1 and D8 MV-NIS for patients (n=10) with disseminated recurrent disease – we will employ a 2 step design
- In the laboratory we are aiming to test the combination of MV-NIS and PD1 inhibition.

Pacific Pediatric Neuro-Oncology Consortium