

Assessment Schedule

	Screening	Period one-blind				Period two-open extension				Follow up	
	Day -28 To -1	Day 1	Week 1	Week 8	Week 12	Week 24	Week 25	Week 32	Week 36	Week 48	Week 49
Target Day	-28 to -1	1	8	56	84	168	175	224	252	336	343
Clinic visits	X	X		X	X	X		X	X	X	
Physical exam	X										
Dispense medication		X			X	X			X		
Neuro-cognitive testing	X				X	X			X	X	
Vitals/wt-ht	X	X			X	X		X	X	X	
Safety labs/Urine	X			X	X	X		X	X	X	
ECG	X				X	X		X	X		
EGG	X					X				X	

Study Commitment

- The study is 12 months in length.
- There will be four to five face to face visits over 24 weeks during the double blinded study.
- There will also be three face to face visits over 24 weeks during the open label treatment.
- Each visit will take up to a full day.



Interested in Participating?

Please reach out to Joanne Carroll CPNP for more information at joanne.carroll@childrens.harvard.edu

**Please note, by emailing this does not mean that you are enrolled in the clinical trial. This is simply to gather information on who might be interested in participating.