

ASPIRE Newsletter

Anticoagulation in ICH Survivors for Stroke Prevention and Recovery



Thank You for Your Efforts for ASPIRE in 2022. Wishing You a Happy and Healthy New Year!

NEXT ASPIRE MONTHLY WEBINAR - JAN 25 3-4 PM ET PLEASE JOIN US TO DISCUSS: Protocol v2.0 Revisions and Procedures Zoom: 937 0999 8648 Passcode: Aspire

RECRUITMENT UPDATE since last Newsletter (11/28)

Randomizing Sites F			
Harborview Medical Center	1		
Inova Fairfax Hospital*	1		
Oregon Health & Science	1		
The Queen's Medical Center	1		
University of Minnesota	1		

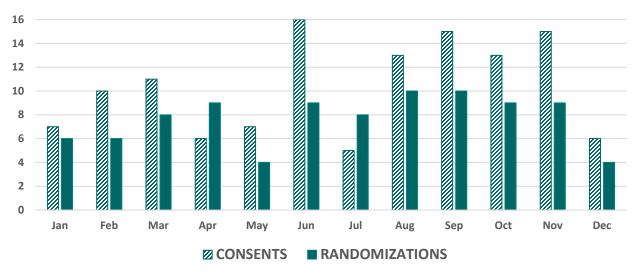
New Pts---Total Enrolled---5147 (21% of goal)

*Congratulations to Inova Fairfax for Enrolling their 1st Subject!





Saqib Chaudhry (PI), Laura Madarasz (PSC), Rachel Dawicki (SC)



2022 Enrollment Activity

ASPIRE Protocol v2.0 Approved by cIRB

MAJOR CHANGES form Protocol v1.4

CHA₂DS₂VAS_c \ge 2 removed as an eligibility requirement (section 4.2)

Change based on recent studies that show patients with ICH are at higher risk for thromboembolic events independent of factors reflected in the $CHA_2DS_2VAS_c$ score. The score will continue to be collected at baseline and used (along with lobar/non-lobar location) as a stratification variable at randomization and for sub-group analysis.

Reimbursement for Subject Time (section 7.)*

Added reimbursement of \$50 for subject time for completion of study contacts (remotely or in-person) to acknowledge the effort required on their part. This will be in addition to reimbursement for travel-associated costs.

Provision of Home Blood Pressure Monitors (section 7.)*

HBPMs will be provided to sites to offer to subjects to facilitate BP assessment during remote contacts.

□ Provision of Pill Organizers (section 7.)*

Pill organizers will be provided to sites to offer to subjects to promote study drug adherence.

Prohibited Medications Revised (section 6.4)

Brings protocol into conformity with new list of prohibited medications that includes drugs other than anticoagulants and antiplatelets (i.e., combined P-gp and strong CYP3A4 inhibitors or inducers).

*REMINDER: You will not be able to implement Protocol v2 until your site-specific Informed Consent Document has been revised to reflect the changes marked with asterisk above and it has been approved by the cIRB.

If you have not received an email NCC regarding your revised ICD by 12/23/2022, please contact ASPIRE@YALE.EDU.

Updated MOP (v6) that reflects Protocol v.2.0 is posted in ASPIRE Toolbox.

REVISED Concomitant Medication Forms

Implemented in WebDCU

- At Screening visit, complete Prior Medications form (F306).
- At Baseline visit, and for subsequent visits, complete Concomitant Medications Log (F288).

RANDOMIZATIONS BY RCC/SITE AND YEAR

RCC	SITE	2022	2021	2020	RCC	SITE	2022	2021	2020
Case Western	Cleveland Clinic		1		U Michigan	McLaren Flint	1		
	MetroHealth Medical Center		1			McLaren Macomb	1		
	UH Cleveland	3				University of Kentucky	1		
	WVU Healthcare Ruby	1			U Minnesota	HealthPartners Methodist	1		
Columbia	Kings County Hospital Center	1				Regions Hospital	1		
	NYP Columbia University	1				University of Minnesota	2		
	NYP Weill Cornell	1			U Penn	Abington Memorial	2		
MUSC	Augusta University	1	1			Hospital of U of Pennsylvania	2	1	
	MUSC		2			Temple University Hospital	1		
	Moses H. Cone	1			U Pitt	UPMC Presbyterian Hospital	2	2	1
	Prisma Health Greenville	2	2		U Utah	University of Utah			1
Mass General	Baystate Medical Center	2			U Washington	Harborview Medical Center	2		1
	Beth Israel Deaconess	1			UAB	University of Alabama	1	2	
	Massachusetts General	2				University of South Alabama	1		
	The University of Vermont	3			UCLA	Cedars-Sinai		1	
MedStar	Inova Fairfax Hospital	1				Kaiser Permanente Los Angeles		2	
	MedStar Georgetown	1	1			PIH Health Hospital - Whittier	1		
	UVA Medical Center	1	1			UC Davis	1		
Mount Sinai	Maimonides Medical Center	1				UC Irvine	3	3	
	NYU Langone - Brooklyn	3	2			University of New Mexico	2	3	
Non Network	Morton Plant Hospital	1			UCSD	Ochsner Medical Ctr	1	1	
	University of North Carolina	2			UCSF	Kaiser Permanente Sacramento		1	
	Vassar Brothers	1				The Queen's Medical Center	2		
Stanford	Oregon Health & Science	5	1	1	UTHSC Houston	Memorial Hermann Texas	1		
	Providence St. Vincent	1				OU Medical Center	1	1	
	Stanford University		1			St. John Medical Center	2		
U Chicago	Central DuPage		1			U of Texas HSC San Antonio		1	
	Rush University	2			Wake Forest	Wake Forest Baptist	3	2	1
	University of Chicago	2			Washington U	Barnes Jewish Hospital	1		
U Cincinnati	OSU Wexner		1			Cox Medical Center South	1		
	University of Cincinnati M	1	2			OSF St. Francis Medical Center	1		1
U Iowa	University of Iowa	2	1	3	Yale	North Shore		1	
	University of Nebraska	2				Rhode Island Hospital	2		
U Miami	Jackson Memorial		1			Yale New Haven Hospital	7	3	1
	Mayo Clinic			1					
	Tampa General		1		TOTAL		92	44	11

ASPIRE CONTACT INFORMATIONASPIRE@YALE.EDU24/7 Hotline: (800) 618-0643Principal InvestigatorsKevin Sheth (443) 615-4729 Hooman KamelProgram ManagersCristina Francois [NCC] (513) 558-3960

Catherine Viscoli [Yale] (203) 927-0443