ASPIRE Newsletter

Anticoagulation in ICH Survivors for Stroke Prevention and Recovery

April 25, 2022, Vol 3. Issue 4

ASPIRE Monthly Webinar → Wednesday April 27 3-4pm ET

TOPIC: Functional and Cognitive Outcomes after ICH

with Alessandro Biffi, MD

Director, Aging and Brain Health Research (ABHR) Group, Massachusetts General Hospital

Zoom: 951 0504 2660 Passcode: aspire

Recruitment Update

9 **Randomizations Since Our Last Newsletter**

RANDOMIZING SITES

Kings County, Brooklyn
Memorial Hermann Texas
OU Medical Center
Prisma Health Greenville
Rhode Island Hospital
Rush University
St. John Medical Center, Tulsa
UH Cleveland
Yale

ASPIRE Participants: 82

Congratulations for 1st Randomizations!

NYC HEALTH+ HOSPITALS | Kings County

Monica Tita (PSC), Susan Law (PI), Yelena Ilyasova (SSC)

Ascension St. John

Rahul Rahangdale (PI), Melanie Arnold (PSC), Holly Wall (SSC), Errol Gordon (SubI)

RUSH

Rima Dafer (PI) [*pictured*], Harley Skorpenske (PSC), Patricija Kirvaitis (SSC)

Rhode Island Hospital
Lifespan. Delivering health with care.®

Michael.Reznik (PI) [*pictured*], Catrina Elizardo (PSC)

Status of ASPIRE Recruitment

So far in 2022, consents have been averaging about 10 per month and randomizations about 7 per month.

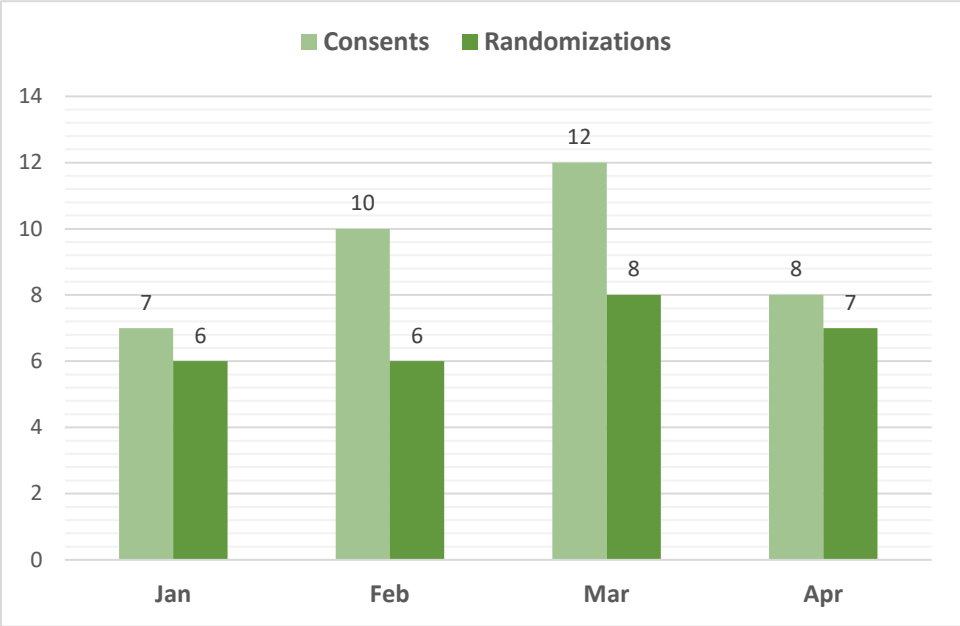
In the coming months, our goal is to show that our site network can randomize at least **10 subjects each month**!

Please remember to:

1. Consent in the hospital
2. Immediately develop a randomization plan!

Please reach out to us for advice whenever you find a patient with ICH and Afib – aspire@yale.edu

Please keep up your efforts for ASPIRE!



CHECKLISTS for ENROLLMENT AND RANDOMIZATION have been REVISED and POSTED in ASPIRE Toolbox

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BASELINE VISIT AND RANDOMIZATION CHECKLIST

Subject:_____

Randomization can occur from post-stroke day 14 through 180. Calendar day (12:00 a.m. through 11:59 p.m.) of index ICH onset is considered post-stroke day 0. If onset is unclear, day of 1st presentation for medical care is considered post-stroke day 0.

Baseline Visit

Baseline visit assessments should be completed immediately preceding randomization but may be performed anytime between 2 days prior to randomization and until study drug is dispensed.

☐Medical History Review: Screen current medical records and/or interview for interval events that affect eligibility
☐Eligibility Confirmation by PI or Sub-I (F101)
☐Concomitant Medications (F303): Review medications taken at time of study drug initiation
☐Blood Pressure Assessment (F117)
☐Modified Rankin Scale (F144): Complete worksheet; obtain from proxy if necessary
☐Questionnaires: Covid-19 (F309), Alcohol and Tobacco Use (F501), Relevant History (F503)

Randomization and Starting Study Drugs

Study drug should be started on the day of randomization but must be started within 48 hours of randomization.

☐**Patient confirmed to meet all study criteria and agrees to start study drugs**
☐Randomization Form completed (F102)
☐Study drugs dispensed (F512 and F513)
☐Subject/LAR given Wallet Alert Card, Participant Information Sheet, Discouraged and Prohibited Medications List

Scheduling Follow-up Visits

Follow-up visits to assess SAEs, clinical outcome events, mRS, blood pressure, eligibility for study drugs, study drug adherence, and concomitant medications should be arranged for every 90 days (±5) after randomization using Visit Scheduler.

☐Visits scheduled and reviewed with subject/LAR
☐Subject/LAR given visit schedule and contact information for study team

Coordinator Signature	**Date**

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ELIGIBILITY AND ENROLLMENT CHECKLIST

Subject:_____

Confirmation of Eligibility

☐Eligible ICH confirmed by CT or MRI
☐Non-valvular atrial fibrillation confirmed
☐$CHAD_2DS_2$-VASc score 2 or greater (F304)
☐Central review completed (*pt. age/sex, clinical context, ICH location sent to ASPIRE@yale.edu*)
☐Patient meets all inclusion criteria and does not meet any exclusion criteria (F101) ***OR*** ☐Screen failure*
**Submit Screen Failure form if patient has ICH and AF and is not consented due to excluded condition or refusal.*

For ASPIRE, ICH is a focal collection of blood within brain parenchyma or ventricular system documented on CT or MRI.

Informed Consent

☐Person who obtained consent assigned this responsibility on DOA
☐Most recently cIRB-approved consent document used
☐If patient lacked cognitive capacity to consent, appropriate LAR used
☐If LAR used, reason documented in medical/research record (*per local procedures*) and Informed Consent CRF
☐Patient or LAR personally signed and dated document in all required places
☐Impartial witness used for consent process if any of following situations applied:
☐Patient illiterate ☐Patient physically incapable of signature
☐Patient visually impaired ☐Translated cIRB-approved Short Form consent used
☐If patient/LAR is not English-speaking:
☐Consent conversation conducted in patient/LAR's primary language, ***AND***
☐Fully translated cIRB-approved consent used, ***OR***
☐Translated Short Form used, process witnessed, and ☐Fully Translated consent provided within 30 days
☐Method by which signed consent was obtained:
☐In person ☐Mail ☐Email ☐Fax ☐U Cincinnati REDCap survey ☐Other e-consent
☐Consent obtained prior to any study procedures
☐Copy of signed/dated consent provided to patient/LAR
☐Consent process documented per institutional process
☐Consent obtained for Biobank blood sample ☐Consent refused for Biobank blood sample
☐Sample shipped and entered in WebDCU>Specimen Shipping

Additional Procedures

☐**CONTACT INFORMATION FORM** completed
☐**MEDICAL RECORD RELEASE FORM** signed
☐**SCREENING VISIT CRFs** completed (*see WebDCU>Project Setup>CRF Collection Schedule*)

Coordinator Signature	**Date**	**Principal Investigator Signature**	**Date**

Please Use the Checklists!

RANDOMIZATIONS BY SITE AND YEAR

SITE	2020	2021	2022	
Augusta University Medical Center		1		
Beth Israel Deaconess Medical Center			1	
Cedars-Sinai Medical Center		1		
Central DuPage Hospital		1		
Cleveland Clinic		1		
Harborview Medical Center	1		1	
Hospital of the University of Pennsylvania		1		
Jackson Memorial Hospital		1		
Kaiser Permanente Los Angeles Medical Center		2		
Kaiser Permanente Sacramento Medical Center		1		
Kings County Hospital Center			1	
Mayo Clinic	1			
MedStar Georgetown University Hospital		1	1	
Medical University of South Carolina University Hospital		2		
Memorial Hermann Texas Medical Center			1	
MetroHealth Medical Center		1		
Moses H. Cone Memorial Hospital			1	
NYU Langone Hospital - Brooklyn		2	2	
North Shore University Hospital		1		
OSF St. Francis Medical Center	1			
OSU Wexner Medical Center		1		
OU Medical Center		1	1	
Ochsner Medical Center - Main Campus		1		
Oregon Health & Science University Hospital	1	1	1	
Prisma Health Greenville Memorial Hospital		2	1	
Rhode Island Hospital			1	
Rush University Medical Center			1	
St. John Medical Center			1	
Stanford University Medical Center		1		
Tampa General Hospital		1		
The Queen's Medical Center			1	
The University of Vermont Medical Center			2	
UC Davis Medical Center			1	
UC Irvine Medical Center		3		
UH Cleveland Medical Center			2	
UPMC Presbyterian Hospital	1	2		
UVA Medical Center		1	1	
University of Alabama Hospital		2		
University of Chicago Medical Center			2	
University of Cincinnati Medical Center		2	1	
University of Iowa Hospitals & Clinics	3	1		
University of Nebraska Medical Center			1	
University of New Mexico Hospital		3		
University of Texas Health Science Center San Antonio		1		
University of Utah Healthcare	1			
Wake Forest Baptist Medical Center	1	2	1	
Yale New Haven Hospital	1	3	1	
	11	44	27	82

--REMINDER--

Please review/revise your ASPIRE DOA

The following **RESPONSIBILITIES** can now only be assigned to **site PI or SubI**:

- **C – Determine eligibility** (i.e., *confirm* eligibility)
- **F – Report adverse events** (i.e., *assess* AE)

Investigators entered on CRFs and DOA responsibilities:

- Investigator confirming eligibility (**F101 Eligibility: Qd1-2**) must have **responsibility C** on DOA
- Investigator reporting adverse event (**F104 Adverse Event: Q18**) must have **responsibility F** on DOA

Note: Team member with **responsibility E – Complete case report forms** can enter data for F101/F104.

For instructions on how to revise DOA responsibilities see page 11 of WebDCU User Manual v14.0.

ASPIRE CONTACT INFORMATION

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