Minnesota Spoke Splash

Welcome!

The Minnesota Spoke Splash is the monthly newsletter of the Minnesota NETT Hub. If you know of others who should receive this newsletter directly, if you would like to change your email subscription, or if you have comments or suggestions, please submit them to Marinda Bland (blan0181@umn.edu).

CHANCE v. POINT Trial: What is the difference?

Since February 2013, when the CHANCE trial data was released, there have been a number of articles about the two trials. Here is a quick review of the differences and perhaps talking points for subjects and/or families.

CHANCE was a randomized controlled trial conducted in China. The healthcare standards are much different in China and the subtypes of stroke are different. This population metabolizes the drug clopidogrel differently which may limit its effectiveness.

CHANCE trial tested the hypothesis that a brief period of dual antiplatelet therapy given to patients with a high risk TIA or minor ischemic stroke would reduce the rate of early recurrent stroke in these patients.

POINT is a randomized clinical trial seeking to test the same hypothesis. The trial will be conducted at 150 U.S. Sites and approximately 60 international sites.

Both trials use aspirin plus study drug (clopidogrel or placebo) daily for 90 days.

Differences: POINT uses 600 mg of clopidogrel/placebo as a loading dose at randomization (twice the dosage used in the CHANCE trial). POINT recommends 50-325 mg of Aspirin daily v. CHANCE recommendation of 75 – 300 mg of Aspirin daily.



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Findings from CHANCE: Risk of recurrent stroke was significantly lower in the dual antiplatelet arm without a significant increase in serious bleeding events.

The risk of recurrent stroke in the first 90 days was 32% lower with absolute reduction $\sim 3.5\%$. The rate of hemorrhagic stroke was the same (0.3%). The risk of any bleeding was 2.3% in the dual antiplatelet group v. 1.6% with aspirin alone and the risk of severe bleeding was about 0.2% in both groups. (Source: neuroicudoc, Alexander Flint)



One of the tricky aspects of ProTECT eligibility is getting an accurate GCS. Anytime you can quickly checking in with EMS (upon arrival) to get the 3 elements confirmed: eyes, verbal and motor, we can be assured that the documentation will match up for eligibility. With the delay in receiving the final EMS run sheet report, it is very important to verify the 3 GCS elements in person if at all possible.

ProTECT

Progesterone for the Treatment of Traumatic Brain Injury

Last week we hosted study monitors Andrace Deyampert (all 3 sites) and Bethany Lane (Regions only). They reviewed all enrollments through 6 months at all three ProTECT sites in preparation for the datalock in September. They set the bar high for themselves with plans to review all patients enrolled before March 1, 2013 from enrollment to 6-month visit.

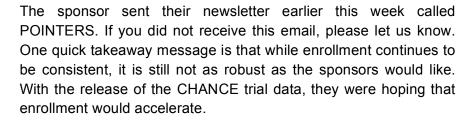
The visit went very well at all sites with a shout out to Regions for their exemplary review. Bethany said the visit "made her month" and she was very impressed. Thanks in advance to all coordinators for quickly responding to the DCR's. They will all need to be closed out by the end of August at the latest.

ProTECT Minnesota Spokes Enrollment Summary		
Spoke	Active	Enrollments
Hennepin County Medical Center	09/03/2010	18
Regions Hospital	11/04/2010	51
North Memorial Medical Center	09/02/2011	7

ProTECT National Hub Enrollment Ranking			
Total Enrollment Nationwide:	801	Enrollment Goal:	1140
Rank	Hub	Enrollment	
1	Arizona	85	
2	Emory	83	
3	Cincinnati	79	
4	Minnesota, Stanford	76	

POINT

Platelet-Oriented Inhibition in New TIA and minor ischemic stroke Trial



On the other hand, it has been mentioned recently that UCSF (the sponsor) is seeking funding to increase the total enrollment target from 4150 to 5860. The larger recruitment goal will hinge on the availability of additional funding for the trial.

Thanks again to United for their latest enrollment in July.



We are looking forward to activating both Abbott Northwestern Hospital in Minneapolis and University of Kansas Medical Center in Kansas City, KS in the next month!

POINT Minnesota Spoke Enrollment Summary		
Spoke	Active	Enrollment
Hennepin County Medical Center	June 2010	19
UMMC - Fairview	November 2010	10
Fairview Southdale Hospital	July 2010	8
Regions Hospital	January 2012	27
Ridgeview Medical Center	February 2012	1
United Hospital	August 2012	3

POINT National Hub Enrollment Ranking				
Total Enrollment Nationwide: 1581 Total Enrollment Goal: 4150			60	
Rank	Hub		Enrollment	
1	UPenn		141	
2	Wayne State		83	
3	Minnesota		68	
4	Cincinnati		67	



SHINE

Stroke Hyperglycemia Insulin Network Effort

There are no new issues to report. This is another study where recruitment is behind its goal. The glucose eligibility requirement has limited enrollments (> 150 for unknown T2DM and > 110 for known T2DM). The measurement has to be done by POCT and not use serum glucose results.

SHINE Minnesota Spoke Enrollment Summary			
Spoke	Active	Enrollment	
UMMC - Fairview	December 2012	3	
HCMC	March 2013	0	

SHINE National Hub Enrollment Ranking			
Total En	Total Enrollment Nationwide: 178 Total Enrollment Goal: 1400		
Rank	Hub	Enrollment	
1	Emory, NYP	23	
3	Kentucky	14	
4	Temple	13	
5	Ohio State	10	
6	Texas	9	
7	Pittsburgh/Cincinatti	6	
9	Maryland	4	
10	Minnesota, Wisconsin, Stanford	3	

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POINT

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SHINE

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