

The Impact of “Open for Enrollment” on Recruitment Rates in Acute Trials

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Recruitment into acute (hours) stroke trials

- Availability of treating investigators, study coordinators, and pharmacists.
- Burden of call-in off-hours has been major issue for recruitment in acute stroke trials for a number of years.
- Usually site selection is based upon the number of eligible patients in a registry – often doesn't account for hours of enrollment at a site.
- We have tried to account for this in feasibility assessments by estimating that 25% of potential subjects are lost by lack of enrollment during night and weekends.
 - Example: MOST: Assume 25% lost by eligible patients evaluated in off hours

Opportunity to examine this question with MOST

- Hypothesis: Site recruitment on a per month basis is associated with duration of staff availability for enrollment.

Methods

- We surveyed all Multi-arm Optimization of Stroke (MOST) trial centers open for enrollment to determine which were:
 - open during business hours during Monday through Friday only,
 - business hours 7 days a week,
 - extended hours beyond business hours,
 - 24 hours/7 days a week.
- We also surveyed about pharmacy availability.

Monthly recruitment rate by Site Availability

	Number of sites	Rate per site per month	Standard Dev.	Minimum	Maximum
Screening and enrolling 24/7	18	0.36	0.44	0.00	1.55
Screening and enrolling during business hours M-F	37	0.16	0.22	0.00	0.94
Screening and enrolling during business hours including weekends	3	0.37	0.45	0.00	0.87
Screening and enrolling during extended (late evening) hours	3	0.36	0.07	0.29	0.43
Other	5	0.12	0.16	0.00	0.40

Summary Results

- Sites with the most limited staff availability recruited at a rate of 0.16 participants per month as compared to 0.36 per month for sites with full availability at 24 hours/7 days a week.
- Restriction of pharmacy availability to business hours Monday through Friday was also associated with decreased recruitment rate.

Conclusions

- Maximal recruitment requires full, 24/7 availability.
- Full availability for screening and recruitment should be a critical component for site selection and prediction of needed sites in future acute StrokeNet trials.
- Methods to increase financial support for effort outside business hours is a potential method to enhance recruitment into acute stroke trials.