

SUMMARY
CLEAR III DSMB MEETING
October 19, 2011
Washington, DC

Attendees:

DSMB: R. Carter (chairman), K. Becker, J. Torner

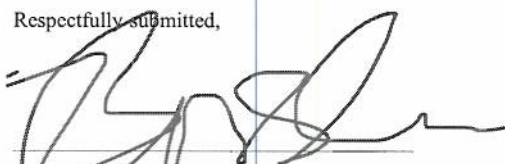
Investigators: D. Hanley (PI), P. Keyl, K. Lane, S. Mayo, N. McBee (by telephone), J. Muschelli, C. Thompson, R. Thompson, G. Yenokyan, A. Wentz

NINDS: P. Gilbert

Recommendations:

1. As no safety or performance issues were identified, the trial should proceed as planned.
2. The DSMB would like to pursue the issue of whether the effectiveness of tPA may be compromised when shipped to foreign countries. Therefore, please provide the DSMB with an analysis comparing the two treatment groups on the range of clot removal (both as % removal and as volume remaining) by geographic region. Also do this analysis for centers where the tPA shipment was noted as possibly temperature impaired versus not. Because this issue should be addressed before many more subjects are enrolled, please provide these analyses by the end of November 2011.
3. The DSMB strongly encourages sites to establish systems to screen potential subjects in real time rather than through weekly surveillance of medical records. This issue affects both study accrual and generalizability of the study sample.
4. Future DSMB data reports should include age and NIHSS in the baseline demographics table.
5. The DSMB will schedule a teleconference for June 2012 to review the next set of data reports. These reports should not include the mRS outcome data.
6. On the June 2012 teleconference, a date will be chosen for a subsequent DSMB meeting involving a formal interim analysis. The meeting will be timed so that 180 day outcome data will be available for at least the first 250 subjects. The following data should be presented for A versus B in the closed session report:
 - a. The mRS outcome data of tables 5.1 and 5.2.
 - b. Survival data presented as Kaplan-Meier curves.
 - c. Data on the incidence and timing of withdrawal of care.
7. The DSMB compliments the investigators for being ahead of schedule on recruitment and for providing a clear and thorough data report.

Respectfully submitted,



Robert S. Carter, MD, PhD
Chairman, CLEAR III DSMB

Date

11/5/11

Accepted by NINDS:



Petra Kaufmann, MD/MSc
Director, Office of Clinical Research, NINDS

Date

11/14/11