Level 4. Full Text Article Data Abstraction Form for Intracranial Hemorrhage Studies

INTRACRANIAL HEMORRHAGE

1. Is this a RCT/Quasi-RCT that reports data on intracranial hemorrhage**? If no, STOP ABSTRACTION**
Yes
No

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check thetick box indicating that:
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)
Yes, briefly describe
No

6. **rFVIIa Dose Information**

rFVIIa Dose	**Dose Units (e.g. mg or ug/kg)**	**Uniform, Mean, or Median Dose? (Use codes U, MN, MD)**	**SD (or Range or IQR), if applicable**	**Number of rFVIIa doses**	**Comments (e.g. specify if variance is range or IQR)**

7. Time/Location of rFVIIa administration
Before or at onset of surgery
During surgery, or after, but while still in OR
Postoperatively (e.g. in ICU), but prior to any reoperation
Return from reoperation for bleeding
All other, describe
Not reported or Unclear

Patient demographics and other information

8. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	**N Control**	**Comments**

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
9. Age					
10. Gender					
11. Admission INR					
12. Hematoma volume on baseline head CT					
13. Time of rFVIIa administration in relation to time of *bleed onset*					
14. Time of rFVIIa administration in relation to time of baseline head CT					
15. Systolic blood pressure					
16. Other demographic 1, specify					
17. Other demographic 2, specify					
18. Other demographic 3, specify					
19. Other demographic 4, specify					
20. Other demographic 5, specify					

21. If different than number of subjects randomized to each group, specify the number of patients with reported baseline data:

N Intervention	N Control	Comments

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
22. Presence of intraventricular hemorrhage on baseline head CT			
23. History of thrombotic/embolic events, specify			
24. Other comorbidity 1, specify			
25. Other comorbidity 2, specify			
26. Other comorbidity 3, specify			
27. Other comorbidity 4, specify			
28. Other comorbidity 5, specify			

Results

29. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
30. Change in hematoma volume from baseline head CT						
31. Other result 1, specify						
32. Other result 2, specify						
33. Other result 3, specify						
34. Other result 4, specify						
35. Other result 5, specify						
36. Other result 6, specify						
37. Other result 7, specify						
38. Other result 8, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
39. Mortality			
40. Functional status/disability			
41. Other result 9, specify			
42. Other result 10, specify			
43. Other result 11, specify			
44. Other result 12, specify			
45. Other result 13, specify			
46. Other result 14, specify			
47. Other result 15, specify			
48. Other result 16, specify			

Harm information

49. Were harms measured?
No. If checked here, stop abstraction

50. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

51. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

52. If harms were adjudicated in any way, specify how.
Blinded panel
Other

53. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thomboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
54. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. **All arterial** thromboembolic events (*without further delineation*)				
56. Myocardial Infarction				
57. Stroke				
58. Mesenteric thrombosis				
59. Renal infarct				
60. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
61. **All venous** thromboembolic events (*without further delineation*)				
62. Pulmonary embolism				
63. Deep vein thrombosis				
64. Mesenteric vein thrombosis				
65. Portal vein thrombosis				
66. Thrombosis in right-side chamber of heart				
67. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
68. **All instrument-related** thromboembolic events (*without further delineation*)				
69. ECMO-related thromboembolic events				
70. Arterial line clot				
71. Venous line clot				
72. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
73. Multi-organ failure				
74. Cardiogenic shock/need for balloon pump				
75. Respiratory failure/ARDS				
76. Renal failure				
77. Sepsis				
78. DIC				
79. Other event #1, specify				

80. Other event #2, specify				
81. Other event #3, specify				
82. Other event #4, specify				
83. Other event #5, specify				

84. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.