Level 4. Full Text Article Data Abstraction Form for Traumatic Bleeding Studies

TRAUMA

1. Is this a RCT/Quasi-RCT that reports data on trauma? **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			
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Subjects lost to follow-up or withdrawn			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. **What types of trauma are included in this arm of the study?**
Blunt trauma
Penetrating trauma
Traumatic brain injury
Other, specify

7. **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 Rangeor IQR), if applicable**	**Number of rFVIIa doses**	**Comments (e.g. specify if variance is range or IQR)**

8. Describe the timing and location of rFVIIa administration below:

Patient demographics and other information

9. 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)
10. Age					
11. Male sex (n)					
12. Weight (or BMI or body surface area, specify units)					
13. Injury Severity Score (ISS)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					

17. If different than the 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)
18. Acidosis			
19. Abnormal INR			
20. Other comorbidity 1, specify			
21. Other comorbidity 2, specify			
22. Other comorbidity 3, specify			

Results

23. 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

Continuous variable

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)
24. RBCs transfused in 24h (packed units)						
25. FFP transfused						
26. ICU time (days)						
27. Change in intracranial hematoma volume (mL)						
28. Other result 1, specify						
29. Other result 2, specify						

Categorical variable

Event	N Intervention	N Control	Comments (e.g. specify other variable)
30. Mortality within 24h			
31. Mortality within 30d			
32. Number of patients requiring transfusions, specify			
33. Need for return to OR/surgical re-exploration			
34. Other result 3, specify			
35. Other result 4, specify			

Harm information

36. Were harms measured?
No. If checked here, STOP abstraction

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

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

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

40. 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
41. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
42. **All arterial** thromboembolic events (*without further delineation*)				
43. Myocardial Infarction				
44. Stroke				
45. Mesenteric thrombosis				
46. Renal infarct				
47. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
48. **All venous** thromboembolic events (*without further delineation*)				
49. Pulmonary embolism				
50. Deep vein thrombosis				
51. Mesenteric vein thrombosis				
52. Portal vein thrombosis				
53. Thrombosis in right-side chamber of heart				
54. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. **All instrument-related** thromboembolic events (*without further delineation*)				
56. ECMO-related thromboembolic events				
57. Arterial line clot				
58. Venous line clot				
59. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. Multi-organ failure				
61. Cardiogenic shock/requirement for balloon pump				
62. Respiratory failure/ARDS				
63. Renal failure				
64. Sepsis				
65. DIC				
66. Other event #1, specify				
67. Other event #2, specify				
68. Other event #3, specify				
69. Other event #4, specify				
70. Other event #5, specify				

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