Level 4. Full Text Article Data Abstraction Form for Cardiac Surgery Studies

CARDIAC SURGERY

1. Is this a RCT/Quasi-RCT that reports data on cardiac surgery? **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Subjects lost to follow-up or withdrawn			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 the tick 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. **Type (s) of surgery performed (for adults) (check all that apply)**
Multiple surgeries
CABG
Cardiac transplantation
Single valve repair/replacement
Any aortic
All Other, specify
No cardiac surgery for adults

7. **Type (s) of surgery performed (for child) (check all that apply)**
Reoperation (any type)
Correction of congenital heart disease
All other, specify
No surgery perfomed in child

8. **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)**

9. 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

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

N Intervention	N Control	Comments

Variable	Mean (or Median) Intervention	SD (or Range or IQR Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
11. Age					
12. Gender					
13. Weight (or BMI or body surface area, specify units)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					
17. Other demographic 4, specify					

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
18. Emergency surgery			
19. Previous cardiac surgery			
20. History of thrombotic/embolic events, specify			
21. Diabetes			
22. Renal failure			
23. CHF			
24. COPD			
25. Hypertension			
26. Other comorbidity 1, specify			
27. Other comorbidity 2, specify			
28. Other comorbidity 3, 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

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)
30. RBCs transfused in 24h (packed units)						
31. FFP transfused						
32. Blood loss (or chest tube drainage) (mLs)						
33. OR time (hours)						
34. Other result 1, specify						
35. Other result 2, specify						
36. Other result 3, specify						
37. Other result 4, specify						
38. Other result 5, specify						
39. Other result 6, specify						

Results categorical variables

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality			
41. Need for return to OR/surgical re-exploration			
42. Number of patients requiring transfusions, specify further			
43. Other result 7, specify			
44. Other result 8, specify			
45. Other result 9, specify			
46. Other result 10, specify			
47. Other result 11, specify			
48. Other result 12, specify			

Harm information

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

50. Was there an explicit follow up time for determination of harms?
Yes, describe

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

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

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

54. 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
55. **All** thromboembolic events				

Arterial Thromboembolic Harms

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

Venous Thromboembolic Harms

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

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
69. **All instrument-related** thromboembolic events (*without further delineation*)				
70. ECMO-related thromboembolic events				
71. Arterial line clot				

72. Venous line clot				
73. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
74. Multi-organ failure				
75. Cardiogenic shock/requirement for balloon pump				
76. Respiratory failure/ARDS				
77. Renal failure				
78. Sepsis				
79. DIC				
80. Other event #1, specify				
81. Other event #2, specify				
82. Other event #3, specify				
83. Other event #4, specify				
84. Other event #5, specify				

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