Level 4. Full Text Article Data Abstraction Form for Liver Transplantation Studies

LIVER TRANSPLANT

1. Is this a RCT/Quasi-RCT that reports data on liver transplant? **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Subjects lost to follow-up or withdrawn			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 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)
Yes, briefly describe
No

6. Special type(s) of surgery performed (check all that apply)
Multiorgan transplantation, specify
Other, specify

7. **rFVIIa Dose Information**

Be sure to indicate in the comments box whether administration of rFVIIa was for preventive or emergent reasons

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)**

8. 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

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. Gender					
12. Weight (or BMI or body surface area; specify units)					
13. Meld score (or Child Pugh classification)					
14. INR					
15. Warm ischemia at time of donor liver					
16. Cold ischemia at time of donor liver					
17. Other demographic 1, specify					
18. Other demographic 2, specify					
19. Other demographic 3, specify					
20. Other demographic 4, specify					

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
21. Emergency surgery (e.g. fulminant liver failure)			
22. Prior liver transplantation of other major liver surgery			
23. Presence of multiorgan failure			
24. History of thrombotic/embolic event, specify			
25. Diabetes			
26. Renal failure			
27. CHF			
28. COPD			
29. Hypertension			
30. Other comorbidity 1, specify			
31. Other comorbidity 2, specify			
32. Other comorbidity 3, specify			

Results

33. 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)
34. RBCs transfused (packed units)						
35. FFP transfused						
36. Blood loss (or chest tube drainage) (mLs)						
37. OR time (hours)						
38. Other result 1, specify						
39. Other result 2, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality, specify			
41. Number of patients requiring transfusion, specify			
42. Need for re-operation or re-transplantation			
43. Other result 3, specify			
44. Other result 4, specify			

Harm information

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

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

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

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

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

50. 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
51. **All** thromboembolic events				

Arterial Thromboembolic Harms

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

Venous Thromboembolic Harms

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

Instrument-related Thromboembolic Harms

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

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
70. Multi-organ failure				
71. Cardiogenic shock/need for balloon pump				
72. Respiratory failure/ARDS				
73. Renal failure				
74. Sepsis				
75. DIC				

76. Other event #1, specify				
77. Other event #2, specify				
78. Other event #3, specify				
79. Other event #4, specify				
80. Other event #5, specify				

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