Level 4. Full Text Article Data Abstraction Form for Prostatectomy Studies

PROSTATECTOMY

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

Study characteristics

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Subjects lost to follow-up or withdrawn			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. Type (s) of surgery performed (check all that apply)
Radial retropubic prostatectoy
Millin prostatectomy
All other, specify

7. **rFVIIa Dose Information**

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/baseline 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. Other demographic 1, specify					
14. Other demographic 2, specify					
15. Other demographic 3, specify					
16. Other demographic 4, specify					

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

Results

27. 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)
28. RBCs transfused (packed units)						
29. FFP transfused						
30. Blood loss (or chest tube drainage) (mLs)						

31. OR time (hours)						
32. Length of hospital stay (days)						
33. Other result 1, specify						
34. Other result 2, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
35. In-hospital mortality			
36. Number of patients requiring transfusions, specify			
37. Need for re-operation or re-transplantation			
38. Other result 3, specify			
39. Other result 4, specify			

Harm information

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

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

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

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

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

45. 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
46. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
47. **All arterial** thromboembolic events (*without further delineation*)				
48. Myocardial Infarction				

49. Stroke				
50. Mesenteric thrombosis				
51. Renal infarct				
52. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

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

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. **All instrument-related** thromboembolic events (*without further delineation*)				
61. ECMO-related thromboembolic events				
62. Arterial line clot				
63. Venous line clot				
64. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
65. Multi-organ failure				
66. Cardiogenic shock/need for balloon pump				
67. Respiratory failure/ARDS				
68. Renal failure				
69. Sepsis				
70. DIC				
71. Other event #1, specify				
72. Other event #2, specify				
73. Other event #3, specify				
74. Other event #4, specify				
75. Other event #5, specify				

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