Level 3. Full Text Data Abstraction Form (Study Information and Quality Assessment)

1. Should this article undergo full text review at Level 3?
Yes
No

2. Where did the study take place? (check all that apply)
U.S., specify city, state
U.S. military warzone
Outside of the U.S., specify country or region
Not reported or unclear

3. What was the source of funding for the entire study (check all that apply)
Novo Nordisk®
Other Industry
Government
Foundation
Other
None
Not applicable (e.g. case report or registry)
Not reported or unclear

4. Did Novo Nordisk support any other aspect of this study (such as registry, persnnel)? For personnel, specify the nature of the relationship/support with Novo Nordisk in the appropriate text box(es)
Statistician
Other Author(s)
Member of the "study group," "research team," or similar designation (and NOT an author on the byline of the paper)
Registry
Other, specify

5. Was the number of enrolling centers reported?
1 center
>1 center
Not reported or unclear
Not applicable (e.g. case report or registry)

6. When did the study take place? Specify as a range in months and years, if given. Leave blank, if unclear.

7. Is this a registry study?
Yes

If this is CASE REPORT/SERIES or REGISTRY study (e.g. any non-comparative study), STOP HERE.

8. What was the maximum length of consistent follow-up (ie, follow-up performed/attempted to be performed for all patients)?
Number of days (or specify other unit (e.g., hours), if different than days)
Not reported or Unclear
Not applicable (e.g. a retrospective study)

9. Was informed consent obtained? (check all that apply)
Obtained from patient or legal representative (e.g., parents for minors)
Determined to not be required by relevant IRB, Ethics Committee, or equivalent
Not obtained for other reason, specify
Not reported or Unclear
Not applicable (e.g. most retrospective studies)

10. Was Institutional Review Board approval (or equivalent) obtained?
Yes
Was determined to not be required, give brief explanation
Not reported or unclear

If this is NOT a RCT/QUASI-RCT, SKIP to Q#13.

11. Were **providers** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)
Partially (e.g., article describes "blinded" treatment and placebo injections but does not provide any other information)
No
Not reported or unclear

12. Were **patients** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)
Partially (e.g., article describes "blinded" treatment and placebo injections but does not provide any other information)
No
Not reported or unclear

13. Were **outcomes assessors** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes
Partially (e.g., article states that assessors had no access to patient names or identifying information)
No
Not reported or unclear

14. Did the study assess the success of blinding in any way?
Yes, specify

15. Were any of the following explicitly defined a priori? NOTE: Must be EXPLICITLY defined in the methods section as chosen/performed at the outset of the study to qualify as being defined as a priori. Refer to L3 GUIDELINES for term codes.
Primary outcome(s), specify:
Secondary outcome(s)
Thromboembolic harms and/or mortality outcome(s), specify:
Other harms outcome(s), specify:
Sample size calculation
Statistical analyses

16. Were the data collected prospectively for this study?
Yes, all data were collected prospectively
Partially, data were collected both prospectively and retrospectively
No
Not reported or unclear
Not applicable (e.g. retrospective case control study)

17. Were any of the following built into the study design? (check all that apply)
Interim analyses
Stopping rules

18. Are you concerned that statistical tests were applied or reported inappropriately? If so, explain why.
Yes, runs multiple analyses without correction (e.g. Bonferroni correction)
Other, explain

19. Were multivariate analyses performed to control for confounding factors?
Yes

20. **FOR COMPARATIVE OBSERVATIONAL STUDIES ONLY (RCTs skip to 21).** Did the study make any attempt to match the control group with the intervention group?
Yes, describe
No
Not Necessary, explain

21. Are you concerned about the potential introduction of bias or lack of generalizability of the study? If so, select all potential problem areas that apply and specify reason. REFER to L3 GUIDELINES for instructions and codes.
Control and intervention groups were not appropriately matched at baseline (e.g. significantly different demographic or comorbidities between the two groups at baseline, REFER to L3 GUIDELINES), specify
Control and intervention groups received differential treatment(s), besides rFVIIa
Differential follow-up time between the control and intervention group, specify
Problem with withdrawals, loss to follow-up, or other missing data, specify
Other reason, specify

For RCTs/QUASI-RCTs, skip to Q24

COMPARATIVE OBSERVATIONAL STUDIES
22. Was the control group contemporaneous or historical?
Contemporaneous
Historical

23. **FOR COMPARATIVE OBSERVATIONAL STUDIES, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?
Yes

RCTs/QUASI-RCTs

24. If the unit of randomization was not the patient, specify the unit here.
Other, specify

25. Was the method of sequence generation for randomization specified? If so, do you have any concerns (explain concerns in text box)?
Yes, was specified, and I have NO CONCERNS
Yes, was specified, but I HAVE CONCERNS, describe
No, was not specified

26. Was the method of allocation concealment described and appropriate?
Yes, it was both described and appropriate (e.g. opaque, sealed envelope)
It was described but was NOT appropriate (e.g., patient name but no other identifying information removed from chart)
No, it was not described
Not applicable

27. If unit of analysis differed from unit of treatment allocation (e.g., providers were randomized, but analyses were of patient outcomes), did authors acknowledge this issue and make appropriate adjustments or conduct sensitivity analyses?
Yes
No
Not applicable (unit of analysis did not differ from unit of treatment allocation)

28. Were analyses performed according to intention-to-treat?
Yes, explicitly stated
Yes, can be inferred (e.g., article states all patients received assigned treatment and follow-up data are available for all patients)
No
Not reported or unclear

29. Skip this question if analyses **were** performed according to intention-to-treat. But, if analyses were NOT performed according to intention-to-treat, give the following information (check all that apply):
Sensitivity analyses were performed
An explanation for why analyses were not performed according to intention-to-treat was given and is summarized here:

30. **FOR RCTs/quasi-RCTs, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?
Yes