

The Danish Warfarin-Dialysis Study: Schedule of appointments

	Screening	Randomization	Monthly review 1 month intervals (+/- 1 weeks)	Quarterly review 3 month intervals (+/- 1 weeks)	Annual review (+/- 1 month)	End of Treatment	Termination of followup End of treatment +6 weeks
Study presentation	•						
ECG / Holter / Event recorder	•						
Baseline blood tests ¹	•						
Pregnancy test ²	•		•				
Informed consent	•						
Registration of baseline data		•					
Medication review		•				•	
International normalized ratio ³			•	•	•	•	
Patient-reported adherence ⁴				•	•	•	
Discontinuation cause						(•)	
Efficacy outcomes ⁵			•	•	•	•	•
Safety outcomes ⁵			•	•	•	•	•
SAEs / SARs ⁵			•	•	•	•	•

1. Plasma-hemoglobin, platelet count, albumin, phosphate, ionized-calcium, parathyroid hormone, c-reactive protein, urea nitrogen, and creatinine.

2. Required in all women of childbearing potential at inclusion and monthly throughout the trial. Women of non-childbearing potential are defined as having no uterus, ligation of the fallopian tubes, permanent cessation of ovarian function due to ovarian failure or surgical removal of the ovaries, or infertility due to natural causes i.e. amenorrhia >12 months or an FSH >40 IU/L

3. Last recorded international normalized ratio

4. Patient-reported adherence: As defined by informed non-adherence > 1 week.

5. Safety and efficacy outcomes, SAEs/SARs will be recorded continuously with reporting of SAEs/SARs to the study sponsor within 24 hours of identification for assessment. Restrospective registration of endpoints in the webapplication REDCap will at minimum be performed within the context of the quarterly reviews.