

Table 2: Study plan

	Screening		Randomised treatment phase								Every 6 months ^a	Final visit ^b
Visit	1	2	3	4	5	6	7	8	9	10		
Month	-14 days	0	3	6	12	18	24	30	36	42		
Informed consent	✓											
Medical history	✓											
Inclusion/exclusion criteria	✓											
Physical examination ^c	✓				✓ ^d							✓
Clinical chemistry ^e	✓				✓ ^f							✓ ^g
CK and ALT ^{h,i}	✓		j	j	✓	j	✓	j	✓	j	✓	✓
Lipid profile and hsCRP ^k	✓		✓		✓		✓ ^l		✓ ^l		✓ ^l	✓ ^l
Dialysis data ^m	✓				✓							
AE review		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Endpoint review			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Study drug dispensing		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Study drug compliance				✓	✓	✓	✓	✓	✓	✓	✓	✓
Concomitant medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

^aIf the study is still ongoing, further check-ups will be performed every 6 months; ^bThe final visit will occur when 620 subjects with major cardiovascular events have been recorded and also if the study is terminated early; ^cResting heart rate, blood pressure, height and weight to be measured after the dialysis session; ^dBlood pressure only to be measured at this visit; ^ePerformed at the central laboratory and including TSH (at baseline only) and complete blood count measured pre-dialysis; ^fHaemoglobin, haematocrit, albumin, calcium and phosphate only; ^gComplete clinical chemistry and blood count only; ^hPre-dialysis CK and ALT to be measured at 12 monthly intervals at central laboratory; ⁱCK may be measured locally if subject suffers from muscle pains at any time during the study; ^jPre-dialysis ALT measured locally every 12 months when not assessed centrally; ^kTC, LDL-C, HDL-C, non-HDL-C, TC/HDL-C, LDL-C/HDL-C, TG, Apo B, Apo AI, Apo B/Apo AI ratio, oxidised LDL and hsCRP will be measured by a central laboratory. Subjects should fast for 6 hours prior to lipid assessment pre-dialysis; ^lOnly changes in TC, LDL-C, HDL-C and TG to be measured; ^mPre- and post-urea measurements to calculate dialysis adequacy, method and duration (hours/week)

ALT: Alanine transaminase, **AE:** Adverse events, **Apo AI:** Apolipoprotein AI, **Apo B:** Apolipoprotein B, **CK:** Creatine kinase, **HDL-C:** High-density lipoprotein cholesterol, **hsCRP:** High-sensitivity C-reactive protein, **LDL-C:** Low-density lipoprotein cholesterol, **TC:** Total cholesterol, **TG:** Triglycerides, **TSH:** Thyroid stimulating hormone