

Appendices 3 Table 1. Schedule of enrollment and study procedures in the XTREME study

Table of Schedule of enrollment and study procedures in the XTREME study		Screening	Randomization	Treatment Phase		
		Visit 0	Visit 1	Visit 2	Visit 3	Visit 4
Visits						
Timelines(week)		-1	0	4	12	24
Treatment Days		7 ±3	0	29 ±7	85 ±7	169 ±7
Informed Consent signed		x				
Eligibility criteria		x	x			
General information	Demographics		x			
	Medical History		x			
	Physical examination		x	x	x	x
Medications	Concomitant medications		x	x	x	x
Clinical assessment	Serum lipids (TG/non HDL-C/TC/LDL-C)		x	x	x	x
	HbA1c		x		x	x
	Plasma Glucose (PG), insulin, C-peptide levels at fasting		x	x	x	x
	Plasma Glucose (PG), insulin, C-peptide levels at 2 h after drinking glucose solution(75g glucose )					x
	Hepatic function (Bilirubin, albumin, liver enzymes)		x	x		x
	Creatine kinase (CK)		x	x		x
	Renal function ( Serum creatinine, BUN ,eGFR)		x	x		x
	Routine blood test		x			x
	Pregnancy test (HCG test for women of childbearing potential only)		x			
	ECG		x			x
	Adverse events		x	x	x	x
Questionnaire	IPAQ		x	x	x	x
Other work	Distributing study drugs		x	x	x	
	Patient medication guidance		x	x	x	
	Patient lifestyle guidance	x	x	x	x	x
	Patient diary dispendance	x	x	x	x	x
	Drug accountability log cards		x	x	x	x
	Retrieving drugs			x	x	x