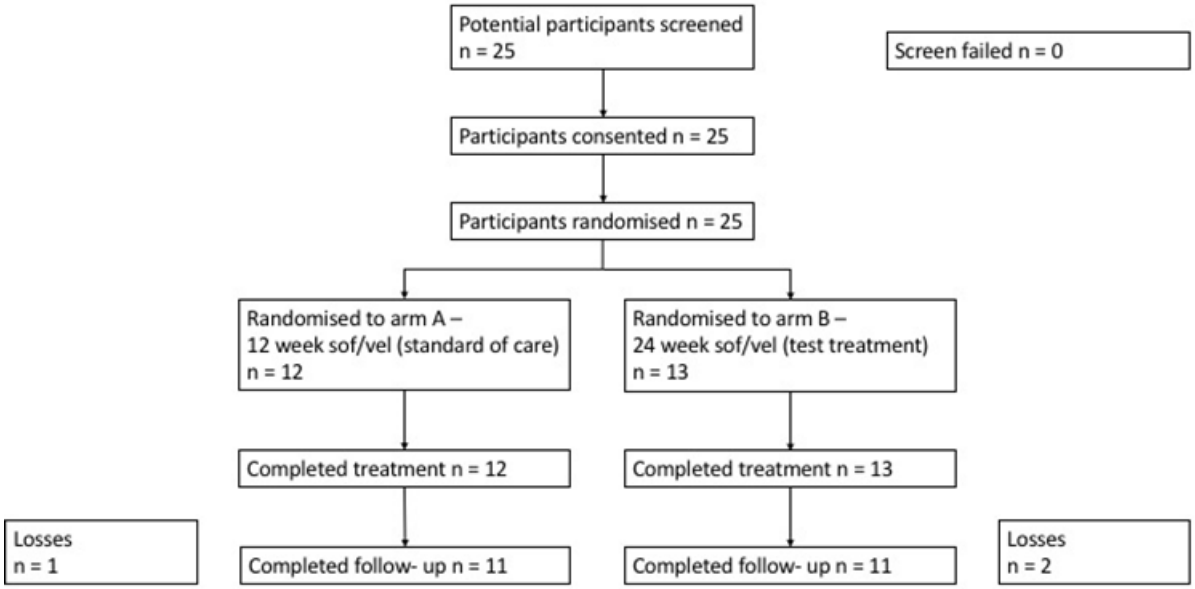
Extend-3 Trial Results Summary – ISRCTN 16857338

Trial flow



Patient baseline characteristics

Baseline characteristics n (%) / mean (range)	12 week sof/vel (arm A)	24 week sof/vel (arm B)	P value
Age (years)	53.7 (30-84)	50.9 (31-78)	0.588
Male	5/12 (41.7)	7/13 (53.8)	0.673
Ethnicity			
– Caucasian	3/12 (25)	5/13 (38.5)	0.695
– Asian	8/12 (66.7)	8/13 (61.5)	0.695
– others / mixed	1/12 (8.3)	0/13 (0)	0.695
Current alcohol user	2/12 (16.7)	3/13 (23.1)	1.0
HCV treatment history			
- naïve	9/12 (75)	13/13 (100)	0.096
- peg interferon/ ribavirin	2/12 (16.7)	0/13 (0)	0.096
- others	1/12 (8.3)	0/13 (0)	0.096
HCV load (iu/mL)	2,977,293 (12,977 – 12,882,500)	2,186,396 (178,000 – 5,816,224)	0.526
Week 2 HCV load (iu/mL)	170 (36-365)	58 (31-124)	0.005 *
Hb (g/L)	131 (112-169)	137 (107-183)	0.348
Platelet count ($x10^9$/L)	148 (56-301)	176 (76-324)	0.372
Sodium (mmol/L)	140.3 (136-143)	139.1 (126-143)	0.372
Creatinine μmol/L	62.4 (47-88)	72.2 (50-101)	0.081
ALT iu/L	92.2 (28-304)	109.7 (25-245)	0.577
Bilirubin μmol/L	20.6 (7-82)	14.7 (3-32)	0.383
Albumin g/L	37.9 (31-46)	37.9 (29-51)	0.998
MELD	7.5 (6-16)	7.1 (6-11)	0.597
Fibroscan score (kPa) *	24.9 (12.1-42.6)	20.8 (12.7-63.9)	0.470
Hepatic decompensation	1/12 (8.3)	1/13 (7.7)	1.0
- past	0/12 (0)	1/13 (0)	1.0
- current	1/12 (8.3)	0/13 (7.7)	1.0

*fibroscan scores were unavailable for 3 patients

Primary outcome

Proportion of patients in each group (12 or 24 weeks of sofosbuvir/velpatasvir) with undetectable HCV RNA (below limit of quantification up to 15 IU/mL) in serum at 12 weeks (+ 4 weeks) after end of treatment (SVR12).

	ITT	mITT
SVR12 – 12 week sof/vel	8/12 (66.7%)	8/12 (66.7%)
SVR12 – 24 week sof/vel	11/13 (84.6%)	11/11 (100%)
Odds ratio (95% CI)	0.379 (0.06 – 2.18)	0 (0 – 1.107)

Secondary outcome measures

Proportion of patients in each group requiring premature treatment discontinuation, reported in patient notes, throughout the treatment period

Proportion of patients in each group who developed serious adverse events, reported in patient notes, throughout the trial period

	SVR12 – 12 week sof/vel N=12	SVR12 – 24 week sof/vel N=13	Difference / Odds ratio (95% CI)
Premature discontinuations	0 (0%)	0 (0%)	
SAEs	2/12 (16.7%)	3/13 (23.1%)	P=1.0 OR 1.48 (0.26-9.7)

Quality of life, measured as SF36 questionnaire scores, in each treatment group at end of study treatment and end of study follow-up (12 weeks post-treatment end)

		SVR12 – 12 week sof/vel N=12	SVR12 – 24 week sof/vel N=13
Physical Component Summary – group mean scores	End of treatment (timepoint 1)	41.124	50.341
	12 weeks post-treatment (timepoint 2)	36.487	48.058
	Mean change	-3.247	-0.338
Mental Component Summary – group mean scores	End of treatment (timepoint 1)	43.129	44.429
	12 weeks post-treatment (timepoint 2)	38.104	46.911
	Mean change	-7.412	3.603

Note – scores are norm-based (50 = population mean, negative mean change = worsening and positive mean change = improvement in patient reported outcome).