able 1. Baseline characteristics of the 72 genotype 1 included patients

	PAR/OMB/rit/DAS + RBV (N = 38)	LVD/SOF + RBV (N = 34)	P-value*
Age at inclusion			
<45 years	12 (32%)	6 (18%)	0.28
≥45 years	26 (68%)	28 (82%)	
Subtype			
1a	27 (71%)	25 (74%)	1.00
1b	10 (26%)	9 (26%)	
Unknown	1 (3%)	0	
Ethnicity¥			
Caucasian	37 (97%)	33 (97%)	1.00
Non-Caucasian	1 (3%)	1 (3%)	
Sex			
Female	9 (24%)	10 (29%)	0.60
Male	29 (76%)	24 (71%)	
Route of infection			
IDU	25 (66%)	20 (59%)	0.34
Non-IDU	10 (26%)	7 (20.5%)	
Unknown	3 (8%)	7 (20.5%)	
Liver fibrosis			
Cirrhosis F4, ≥17 kPa, clinical diagnosed	13 (34%)	13 (38%)	0.07
Severe fibrosis F3/12-16.9 kPa	4 (11%)	10 (30%)	

Mild-moderate fibrosis F1-F2/≤11.9 kPa	21 (55%)	11 (32%)	
HIV status			
Negative	31 (82%)	29 (85%)	0.76
Positive	7 (18%)	5 (15%)	
Hepatitis B status			
Negative	38 (100%)	34 (100%)	
Previous treatment			
No	31 (82%)	27 (79%)	1.00
Yes	7 (18%)	7 (21%)	
Previous response to treatment			
Non-response¶	1 (3%)	1 (3%)	1.00
Relapse§	3 (8%)	3 (9%)	
Viral breakthrough¤	0	1 (3%)	
Termination due to adverse event	3 (8%)	2 (6%)	
Fatigue at baseline			
Grade 1	5 (13%)	11 (32%)	0.14
Grade 2	2 (5%)	0	
Body-mass index#	25.6 ±4.27	25.7 ±3.16	
HCV-RNA level – 10^6 IU/ml	2.35 ±2.75	2.77 ±3.39	
ALT level - U/L			
Median	86.5	74.0	
Interquartile range	49.0-137.0	49.0-124.0	
Platelet count – x 10^9/liter			
Median	206.0	187.5	
Interquartile range	161.0-237.0	126.0-227.0	

Serum albumin – g/liter		
Median	39.0	39.0
Interquartile range	36.0-42.0	37.0-41.0

Plus-minus values are means ± standard deviation.

*Comparisons between treatment groups were done by Fisher's exact test.

¥ Ethnicity was self-reported.

The body-mass index is the weight in kilograms divided by the square of the height in meters.

¶ Non-response to previous pegylated-interferon/ribavirin was defined as: patients received at least 12 weeks of pegylated-interferon/ribavirin for the treatment of HCV infection and did not have a reduction in the HCV-RNA level of at least 2 log10 IU per milliliter at week 12, or they received at least 4 weeks of pegylated-interferon/ribavirin for the treatment of HCV infection and had a reduction in the HCV-RNA level of less than 1 log10 IU per milliliter at week 4.

§ Relapse to previous pegylated-interferon/ribavirin was defined as: patients received at least 24 weeks of pegylated-interferon/ribavirin for the treatment of HCV infection and had an undetectable level of HCV-RNA at the end of treatment or thereafter but a detectable level within 24 weeks after treatment.

¤ Viral breakthrough to previous pegylated-interferon/ribavirin was defined as: HCV-RNA levels initially decreases during treatment with pegylated-interferon/ribavirin (undetectable levels can be seen), followed by a clinical relevant increase while on treatment.

PAR, Paritaprevir; OMB, Ombitasvir, rit, Ritonavir; DAS, Dasabuvir; LVD, Ledipasvir; SOF, Sofosbuvir, IDU, Injecting drug use; ALT, Alanine transaminase.

Table 2.

Current disease of the 72 patients with chronic hepatitis C genotype 1 included in the study

	PAR/OMB/rit/DAS + RBV (N = 38)	LVD/SOF + RBV (N = 34)	P-value*
Current disease			
Yes	27 (71%)	28 (82%)	0.28
No	11 (29%)	6 (18%)	
Hypertension			
Yes	3 (11%)	9 (32%)	0.10
No	24 (89%)	19 (68%)	
Diabetes Type I & II			
Yes	0	3 (11%)	0.24
No	27 (100%)	25 (89%)	
Psychiatric disease			
Yes	6 (22%)	4 (14%)	0.50
No	21 (78%)	24 (86%)	
Arthritis			
Yes	11 (41%)	7 (25%)	0.26
No	16 (59%)	21 (75%)	
Haemophilia			
Yes	2 (7%)	0	0.24
No	25 (93%)	28 (100%)	
Gastro-intestinal disease			
Yes	7 (26%)	8 (29%)	1.00

No	20 (74%)	20 (71%)	
Urological disease			
Yes	1 (4%)	1 (4%)	1.00
No	26 (96%)	27 (96%)	
Lung disease			
Yes	6 (22%)	6 (21%)	1.00
No	21 (78%)	22 (79%)	
Vasculitis			
Yes	0	2 (7%)	0.49
No	27 (100%)	26 (93%)	
Skin disease			
Yes	5 (19%)	3 (11%)	0.47
No	22 (81%)	25 (89%)	
Thyroid disease			
Yes	0	1 (7%)	1.00
No	27 (100%)	26 (93%)	
Edema peripheral			
Yes	1 (4%)	2 (7%)	1.00
No	26 (96%)	27 (93%)	

***** Comparisons between treatment groups were made using Fisher's exact test.

PAR, Paritaprevir; OMB, Ombitasvir, rit, Ritonavir; DAS, Dasabuvir; LVD, Ledipasvir; SOF, Sofosbuvir.

Table 3

Adverse Events and laboratory abnormalities for 72 patients with chronic hepatitis C genotype 1 included in the study

Variable	PAR/OMB/rit/DAS + RBV (n = 38)	LVD/SOF + RBV (n = 34)	Total (N = 72)	P-value*
Any Adverse Event	37 (97%)	33 (97%)	70 (97%)	1.00
Adverse Event leading to treatment discontinuation	1 (2.6%)	1 (3%)	2 (3%)	
Serious Adverse Event	3 (8%)	6 (18%)	9 (12.5%)	0.29
Death	1 (2.6%)	0	1 (1.4%)	
Change in ribavirin dose treatment week 1-12	4 (11%)	8 (24%)	12 (17%)	0.21
Common Adverse Events				
Anemia§	29 (76%)	27 (79%)	56 (78%)	0.78
Fatigue	27 (71%)	26 (77%)	53 (74%)	0.79
Headache	19 (50%)	14 (41%)	33 (46%)	0.49
Pruritus, dry skin or eczema	20 (53%)	13 (38%)	33 (46%)	0.25
Heartburn/abdominal pain/abdominal distention	16 (42%)	11 (32%)	27 (38%)	0.47
Nausea/vomiting	14 (37%)	11 (32%)	25 (35%)	0.81
Upper respiratory infection	13 (34%)	11 (32%)	24 (33%)	1.00
Asthenia/malaise/tremor	13 (34%)	9 (26%)	22 (31%)	0.61
Dyspnea	11 (29%)	10 (29%)	21 (29%)	1.00
Irritability/mood swings/depression	8 (21%)	12 (35%)	20 (28%)	0.20
Insomnia	9 (24%)	8 (24%)	17 (24%)	1.00
Decreased appetite	11 (29%)	4 (12%)	15 (21%)	0.09
Diarrhea	8 (21%)	6 (18%)	14 (19%)	0.77
Dizziness	5 (13%)	3 (9%)	8 (11%)	0.71
Arthralgia	3 (8%)	4 (12%)	7 (10%)	0.70
Muscle spams	3 (8%)	2 (6%)	5 (7%)	1.00
Memory impairment/absent minded	1 (3%)	3 (9%)	4 (6%)	0.34
Affected vision	3 (8%)	1 (3%)	4 (6%)	0.62
Increased appetite	1 (3%)	3 (4%)	4 (6%)	0.34
Tinnitus	3 (8%)	0	3 (4%)	0.24
Herpes outbreak	2 (5%)	1 (3%)	3 (4%)	1.00
Constipation	2 (5%)	1 (3%)	3 (4%)	1.00

Chest pain	1 (3%)	1 (3%)	2 (3%)	1.00
Fungal infection (mouth or vaginal)	2 (5%)	0	2 (3%)	0.49
Laboratory abnormalities#				
Alanine transaminase, grade 2 or 3	0	0	0	
Alkaline phosphatase, grade 2 or 3	1 (2.6%)	0	1 (1.4%)	1.0
Total bilirubin, grade 2 or 3	1 (2.6%)	0	1 (1.4%)	1.0
Hemoglobin				
Grade 1	29 (76%)	23 (68%)	52 (72%)	0.047
Grade 2	0	4 (12%)	4 (6%)	
Grade 3	0	0	0	

*****Comparisons between treatment groups were made using Fisher's exact test.

PAR, Paritaprevir; OMB, Ombitasvir, rit, Ritonavir; DAS, Dasabuvir; LVD, Ledipasvir; SOF, Sofosbuvir.

#The abnormalities here reflect post-baseline laboratory values, regardless of baseline values.

§Anemia was defined as hemoglobin levels below the lower limit of normal range (male: 8.3 mmol/L, female: 7.3 mmol/L).

For alanine transaminase, a level of grade 2 was defined as a value that was 5-10 times the upper limit of normal range, and grade 3 was defined as a value that was more than 10 times the upper limit of normal. For alkaline phosphatase, a level of grade 2 was defined as a value 2-4 times the upper limit of the normal range, and grade 3 was defined as more than 4 times the upper limit of the normal range. A total bilirubin level of grade 2 was defined as 3-10 times the upper limit of the normal range, and grade 3 as a value that was more than 10 times the upper limit of the normal range.

For hemoglobin, a level of grade 1 was defined as 6 mmol/L to less than the lower limit of the normal range, grade 2 as 5.0 to 5.9 mmol/L, and grade 3 as <5.0 mmol/L.