SVR12 Results after 12w Boceprevir+ P/R in the Dutch Acute Hepatitis C in HIV Study

Sebastiaan J. Hullegie[1], Mark A.A. Claassen[1], Guido E.L. van den Berk[2], Jan T.M. van der Meer[3], Joop E. Arends[4], Clemens Richter[5], Dirk Posthouwer[6], Peter P. Koopmans[7], Fanny N. Lauw[8], Bart J.A. Rijnders[1]

[1]Erasmus MC, Rotterdam; [2]OLVG, Amsterdam; [3]AMC, Amsterdam; [4] UMCU, Utrecht; [5]Rijnstate ZKH, Arnhem; [6]MUMC, Maastricht; [7]Radboud UMC, Nijmegen; [8]Slotervaart ZKH, Amsterdam

b.hullegie@erasmusmc.nl; b.rijnders@erasmusmc.nl

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Background

The international epidemic of acute hepatitis C virus (AHCV) continues to spread within HIV+ MSM, with incidence rates between .08 and 1.75%. 24wks of peginterferon(P) (+/- ribavirin(R)) cures 60-70% of them.

The addition of a direct-acting anti-viral drug (DAA) may increase cure rates and allow a shorter treatment. The efficacy and role of the old and new DAA in the treatment of AHCV has not been studied. Furthermore, given the costs of new DAA, almost all European countries currently restrict the use of newer DAA to patients with severe fibrosis or cirrhosis.

This Dutch nationwide study evaluates the efficacy and tolerability of 12w boceprevir+P+R in acute HCV genotype-1 HIV-infected patients.

Methods

- HIV positive MSM were tested for HCV RNA if they presented with an ALAT > upper limit of normal

- Infection date was calculated by retesting stored plasma samples. (CAP/CTM V2, Roche diagnostics)

- HCV genotype 1 infected patients were included and treatment started within 26 weeks after infection

- Boceprevir +P+R were given for 12 weeks, without P/R lead-in

- Virological response was defined as HCV RNA < 15 copies/target not detected

Baseline characteristics (n=57)

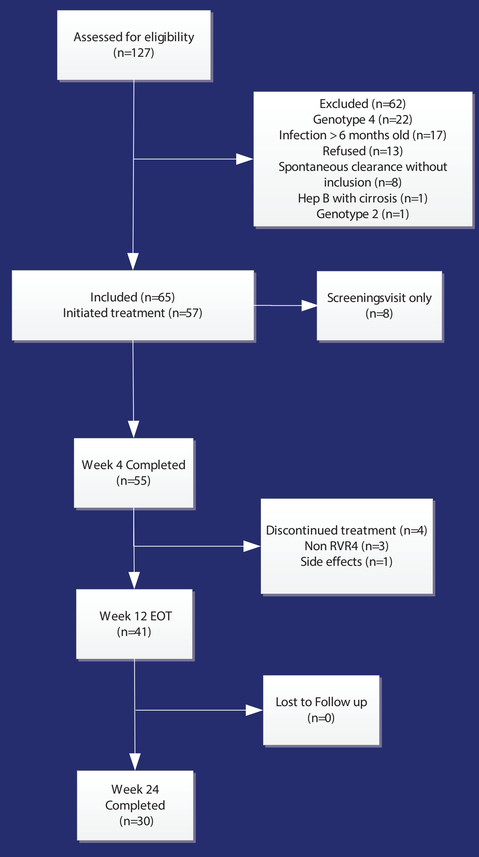
Gender	Male	100	%	
Race	Caucasian	93	%	
	non-Caucasian	7	%	
Genotype	1 a	95	%	
	b	5	%	
IL28B *RS1297*	CC	42,5	%	
	CT	50	%	
	TT	7,5	%	
Age	median	40	years	(IQR 34-47)
CD4 count	median	0,66	E9/l	(IQR 0,45-0,79)
Interval infection-treatment	median	22	weeks	(IQR 16,5-25)
Baseline HCV Load	median	200.000	IU/ml	(IQR 8.375-3.230.000)

Primary endpoint:

Sustained virological response (SVR) 12 weeks after the end of therapy in the RVR4 population

Secondary endpoint:

SVR12 in the intention to treat (ITT) population



Incidence of AHCV in 2014 in the study centers

8304 HIV+ and HCV- MSM were in care
91 AHCV infections were diagnosed

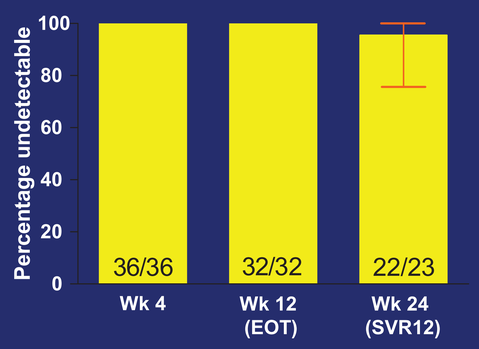
The estimated minimum incidence was therefore 91/8304=11/1000 PYFU (95% CI 8.9-14)

Results

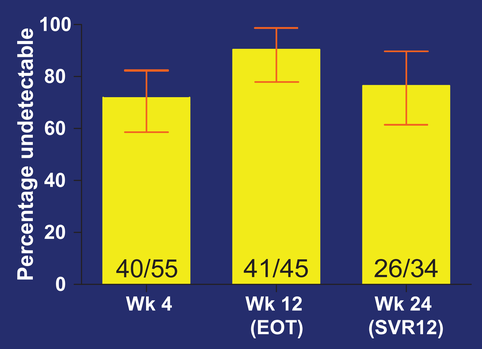
The study is ongoing but fully enrolled with 65 patients included of which 8 cleared HCV spontanuously and 57 started therapy. 34 patients have reached the SVR12 evaluation endpoint.

Three SAE have been reported; 1 myocardial infarction (not related); 1 transient ischemic attack (not related), 1 grade 4 anemia (related). Median amount of AE per patient: grade 1=4, grade 2=1.5 and grade 3=1.

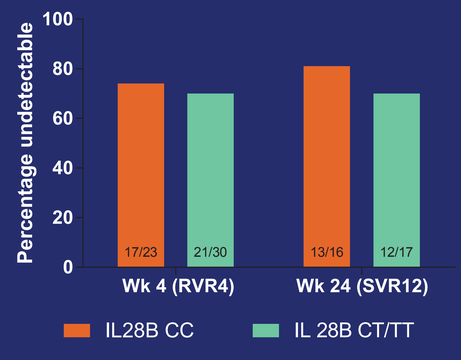
Virological response in RVR4 patients



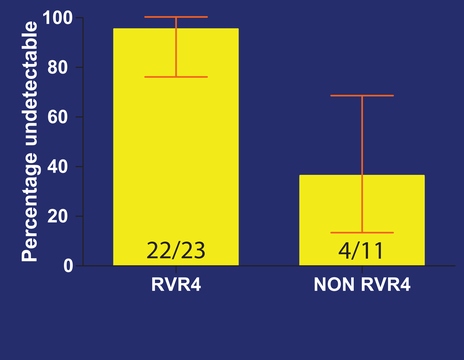
Virological response in ITT patients



Virological response according to IL 28B



SVR12 rate according to week 4 result (ITT)



Conclusion

- Addition of boceprevir to P/R halves therapy duration of acute HCV to 12 weeks
- 95% SVR in RVR4 patients (95% CI 75%-99%)
- 76% SVR in ITT population (95% CI 58%-89%)
- IL28 RS1297 nor RS809 genotype had impact on SVR12 results
- No unexpected side effects were observed
- The DAHHS network allows for a fast evaluation of DAA for the treatment of AHCV