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

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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

Results
The study is ongoing but fully enrolled with 65 patients included of which 8 cleared HCV spontaneously 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 according to IL 28B

Inclusion of patients with advanced fibrosis or cirrhosis.

Virological response in ITT patients

Virological response in RVR4 patients

Virological response according to week 4 result (ITT)

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


dd-12w 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 %
IL28 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)

Incidences 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)

Background
The international epidemic of acute hepatitis C virus (AHCV) continues to spread within HIV+ MSM, with incidence rates between 0.8 and 1.75%.

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

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