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8 WEEKS OF GRAZOPREVIR/ELBASVIR FOR ACUTE HCV: A MULTICENTER CLINICAL TRIAL (DAHHS 2)
Clinical: (K) Hepatitis Viruses and Liver Complications
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Background: The arrival of direct acting antiviral (DAA) therapy for chronic hepatitis C (HCV) infection has led to speculations about HCV elimination. Modeling and real-life data on HCV elimination in well-defined risk groups like HIV-positive MSM have been promising (CROI 2017 LB137/136). However, high reinfection rates and increased sexual risk behavior may become significant obstacles. Another obstacle is the lack of approval of DAA for the treatment of acute HCV. Indeed, few studies evaluated DAA as acute HCV therapy and included a small numbers of patients (n=17 to 26). Sustained virological response (SVR) rates in these studies varied between 32-59% for sofosbuvir/ribavirin and 77-100% for sofosbuvir/ledipasvir. The Dutch Acute HCV in HIV study no. 2 (DAHHS2; NCT02600325) was designed to prove that 1. grazoprevir/elbasvir are effective when given during the acute phase of HCV and 2. treatment can be shortened during acute HCV.
Methods: Single-arm prospective open-label multicenter trial in patients with acute HCV genotype 1 or 4. Fifteen hospitals referred patients diagnosed with an acute HCV to 1 of the 9 DAHHS study centers spread across the Netherlands and Belgium. Patients received 8 weeks of grazoprevir/elbasvir 100/50mg QD. Therapy was initiated no later than 26 weeks after the estimated day of infection. The primary endpoint was SVR 12 weeks post-treatment in the intention to treat population.
Results: From 02/2016 and ongoing, 110 patients with a recently acquired HCV were evaluated for eligibility. 68 were enrolled, 5 patients never initiated therapy (Fig1). Of the 63 patients that started therapy, 53 reached the primary endpoint at the time of abstract submission. All subjects were MSM with a mean age of 47 years and all but 3 were HIV-infected. CD4 at baseline in HIV-infected patients was 600/µl (IQR 474-760) and HIV viral load was <50 c/ml in 97%. The genotype 1a/1b/4 distribution was 62/0/38%. Median HCV viral load at study entry was 3.67E5 IU/ml (IQR 1.95E4-2.00E6) and 16% (n=10/63) of HCV infections were a reinfection. SVR12 was observed in 52 of 53 patients (98%; 95%CI 90-100%). One patient relapsed, but without new NS5a/NS3 compared to his baseline virus. One of the 52 patients had a phylogenetically proven new infection. All 13 patients with a baseline viral load >10E6 IU/ml reached SVR12.
Conclusion: An 8 week course of grazoprevir/elbasvir (a NS3/NS5a combination) is highly effective for the treatment of acute HCV. The results of all 63 patients will be presented.