



PROPOSTE DI STUDI NO PROFIT MULTICENTRICI PROMOSSE DA AISF – CPT

Title:

An Open-Label Study to Explore the Clinical Efficacy of Sofosbuvir With Ribavirin as Pre-Emptive Administration in Transplant-Recipients with Hepatitis C Virus (HCV) active infection

Promoter:

Stefano Faggioli, on behalf of the Italian Association for the Study of the Liver (AISF)

Financial support:

Gilead Sciences

Participants:

All AISF hepatologists involved in the management of liver transplanted patients after local ethic committee approval



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Razionale

Patients with high MELD scores that cannot wait long in the waiting list are those who cannot benefit from antiviral therapy while waiting for transplantation. In this category of patients preemptive antiviral therapy remains a reasonable treatment strategy in order to reduce the likelihood of HCV recurrent hepatitis

Primary Objective

To determine if the administration of a combination of Sofosbuvir and ribavirin to post-OLT HCV subjects for 24 weeks can prevent post-transplant HCV re-infection as determined by a sustained post-transplant virological response (HCV RNA <LLOQ) at 24 weeks post-transplant

Secondary Objective(s) (optional):

- Effect of treatment on HCV-related liver disease histology at 1-year
- To evaluate the HCV RNA viral kinetics during the initial treatment phase (2 weeks, 4 weeks, 8 weeks) and correlation with response rate



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Eligibility:

- Males or females, age > 18 years old
- All transplant patients with HCV active infection at the time of LT
- All genotypes
- MELD score ≥ 25 during waiting list period

Exclusion:

- Patients unable to receive oral therapy
- < 6 months from previous DAA treatment
- CrCl < 30ml/min

Projected Duration of Treatment 24 weeks

Study Duration Up to 48 weeks (up to 24 w treatment + 24 w follow-up)

Start of protocol: after Gilead International Scientific board approval