PROPOSTE DI STUDI NO PROFIT MULTICENTRICI PROMOSSI DA AISF – CPT

Title:

Antiviral treatment with Sofosbuvir plus ribavirin in “waitlisted” patients with HCV-related end stage liver disease (ESLD) without HCC

Promoter:

Pierluigi Toniutto, on behalf of the Italian Association for the Study of the Liver (AISF)

Financial support:

Gilead Sciences

Partecipants:

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

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Rationale

HCV infection is the major indication for liver transplantation worldwide, and its recurrence is virtually universal. Once reinfection is established, progression to cirrhosis can occur in about 25-30% of the recipients within 5 years. Interferon-based antiviral treatments strongly limit number of potentially treatable ESLD patients. The pre-transplant IFN-free treatment aiming to achieve HCV-RNA negativity at transplant could be the preferred strategy.

Objectives

To determine if the administration of a combination of Sofosbuvir plus ribavirin up to the transplant procedure (maximum for 48 weeks) in waitlisted patients with liver cirrhosis 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 Objectives:

MELD score improvement during treatment - removal from waitlist

HCV-RNA kinetics in advanced liver disease

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Eligibility:

- Males or females, age > 18 years old;
- All ESLD patients with HCV active mono-infection included in a waiting list for first OLT (MELD score between 15 and 24 or accepted MELD exceptions)
- All HCV genotypes

Exclusion:

- Patients with known HCC
- < 6 months from previous PI treatment
- Combined liver-kidney transplant
- CrCl <30ml/min

Projected Duration of Treatment up to 48 weeks

Study Duration Up to 72 weeks (up to 48 w treatment + 24 w follow-up)

Start of protocol: after Gilead International Scientific board approval