

RELAZIONE ANNUALE

Titolo dello studio	
“Multicenter, observational retrospective study on thrombocytopenia associated with PEG-IFN alfa- 2a (PEGASYS) or PEG-IFN alfa-2b (PEG-Intron) and Ribavirin treatment of patients with chronic hepatitis C”	
Responsabile (Principal Investigator)	Evangelista Sagnelli
Data di inizio studio (mese/anno)	Settembre 2013
Data presunta di termine studio (mese/anno)	Giugno 2015
Descrizione dell'attività svolta (max 400 parole)	
<p>In this study, our aim was to evaluate the prevalence of thrombocytopaenia that may potentially limit the initiation of treatment with pegylated interferon and ribavirin in a consecutive series of patients with chronic HCV infection who were referred to Italian Infectious diseases and Hepatology/gastroenterology centres for antiviral therapy evaluation and who were otherwise eligible for treatment.</p> <p>The preliminary interim results of these analysis concern the chart data review of 182 pts screened in 9 of the 28 participating centres. In this population 173 (95,05%) started the treatment, 9 pts (4,95%) were excluded at the screening visit and 4 pts of them were TCP related screening failure. During the AVT 46 patients 25,27% of the studied population received a TCP related suboptimal treatment and, the reason for interruption or change was thrombocytopenia for the 45% of these patients (in 50% of the patients AVT was reduced and 50% stopped). Looking at the platelets counts levels used as threshold for starting, modifying or interrupting IFN, the values found in these population appear in line with those suggested by IFN based AVT of HCV patients and by the IFNs prescribing information.</p> <p>In conclusion in our analysis the TCP was found as the main reason of screening failure for AVT in 2.1% of the candidate population which means that every 173 patients who start AVT 4 patients have been excluded for TCP (around 2,3 pts every 100-pts starting AVT per year) Furthermore in the treated population of TCP was considered reason for suboptimal treatment in 45% of pts in AVT. This even preliminary data can contribute to show the real impact of thrombocytopenia in the antiviral treatment of HCV pts.</p>	
Problematiche riscontrate e proposte di soluzione (max 200 parole)	
Lo studio ha raggiunto solo in parte il suo scopo, sia per la mancata approvazione da parte 5 dei 28 Comitati Etici sia per la scarsa o assente collaborazione di numerosi altri Centri. Infatti, dei 23 centri partecipanti ed autorizzati a partecipare sono solo 9 hanno assicurato una sufficiente collaborazione. Si è potuto quindi effettuare solo una valutazione ad interim dei dati, che tuttavia risultano insufficienti per una pubblicazione su rivista internazionale.	