ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 4, 2019

ClinicalTrials.gov ID: NCT02743182

Study Identification

Unique Protocol ID:	QUANTI-B
Brief Title:	HBsAg Loss Adding Pegylated Interferon in HBeAg-negative Patients
Official Title:	HBsAg Loss Adding Pegylated Interferon Alfa-2a in HBeAg-negative Patients Treated With Nucleos(t)Ide Analogues.
Secondary IDs:	

Study Status

Record Verification:	September 2019
Overall Status:	Completed
Study Start:	January 2015 []
Primary Completion:	October 2018 [Actual]
Study Completion:	November 2018 [Actual]

Sponsor/Collaborators

Sponsor:	José Antonio Carrion
Responsible Party:	Sponsor-Investigator Investigator: José Antonio Carrion [jcarrion] Official Title: Dr. Affiliation: Parc de Salut Mar
Collaborators:	Instituto de Salud Carlos III

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2014/5787/I Board Name: Comité Ético de Investigación Clínica del Parc de Salut Mar Board Affiliation: ParcSM Phone: 933160677 Email: ceic-psmar@imim.es Address: Dr. Aiguader, 88, 08003, Barcelona, Spain

Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	Chronic hepatitis B (CHB) affects more than 350 million people worldwide. The most common form in Europe is CHB HBeAg-negative. Antiviral treatment of CHB HBeAg-negative patients includes chronic administration of nucleos(t)ide analogues (NUC) or pegylated interferon (PegIFN) during 12 months. Typically, PegIFN allows immune control of CHB and antigen “s” (HBsAg) loss in around 4% of patients compared to less than 0,1% using NUC. Recently, it has been described that HBsAg quantification (HBsAg-q) is useful to identify patients with high probability to lose HBsAg during follow-up. In addition, a proof-of-concept study with nine HBeAg-negative patients receiving NUC showed that adding PegIFN (16 weeks) achieved HBsAg loss in one patient (11%). The aim of our study is to evaluate the efficacy and safety adding PegIFN (48 weeks) in treated HBeAg-negative patients with NUC.
Detailed Description:	

Conditions

Conditions:	Chronic Hepatitis B (HBeAg-negative)
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Other
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Non-Randomized
Enrollment:	119 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Pegylated interferon alfa-2a adding Pegylated interferon alfa-2a (180 microgs / week during 48 weeks) in HBeAg-negative patients receiving nucleos(t)ide analogues	Drug: Pegylated interferon alfa-2a
No Intervention: Control HBeAg-negative patients receiving nucleos(t)ide analogues	

Outcome Measures

Primary Outcome Measure:

1. Number of patients with HBsAg loss
   HBsAg will be evaluated one year after treatment completion (96 weeks). Efficacy will be calculated as a proportion (rate of patients with HBsAg loss/treated patients)

   [Time Frame: 1 year after treatment completion]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Chronic hepatitis B (HBeAg-negative)
- Signed inform consent
- Aged > 18

Exclusion Criteria:

- Contraindications for Pegylated interferon (cirrhosis, pregnancy, others)
- Previous treatment with interferon or Pegylated interferon
- Previous HBsAg loss
- Treatment duration with Nucleos(t)ide analogues less than 2 years
- Poor adherence to Nucleos(t)ide analogues

Contacts/Locations

Central Contact Person:	
Central Contact Backup:	
Study Officials:	
Locations:	

IPDSharing

Plan to Share IPD:	

References

Citations:	
Links:	
Available IPD/Information:	