ORPHEE - Prospective cohort study on the impact of insulin resistance on sustained virological response to Pegasys® and Copegus® treatment in patients with Chronic Hepatitis-C

Head :Medical data center

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General

Identification

Detailed name	Prospective cohort study on the impact of insulin resistance on sustained virological response to Pegasys® and Copegus® treatment in patients with Chronic Hepatitis-C
Sign or acronym	ORPHEE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22790

General Aspects

Medical area	Infectious diseases
Study in connection with Covid-19	No
Pathology (details)	Chronic hepatitis-C
Health determinants	Medicine
Keywords	Copegus® treatment

Scientific investigator(s) (Contact)

Name of the director	Medical data center
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

Funding	
Funding status	Private
Governance of the database	
Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Primary objective : To describe in real-life conditions the insulin resistance and its impact on SVR in patients presenting with chronic hepatitis C and treated with Pegasys® and Copegus®. Secondary objectives : - To describe patients' characteristics at inclusion - To describe the predictive factors influencing virological response under treatment at W4 (rapid virological response, RVR), at W12 (early virological response, EVR), and 24 weeks after the end of treatment with Pegasys® (sustained virological response, SVR) - To describe the constitutive parameters of metabolic syndrome during the study period - To describe the management of chronic hepatitis C and insulin resistance - To describe the changes in patients' quality of life

	during the study period - To describe the serious and non-serious adverse events occurring during the study period.
Inclusion criteria	Inclusion criteria : - Adult patient (age >=18 years) - Suffering from chronic hepatitis C (detectable blood HCV RNA) - For whom the specialist had decided to initiate dual therapy with Pegasys® and Copegus® - Who received both oral and written information about the study, without any objections for the use of his/her personal data.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	B15-B19 - Viral hepatitis
Gender	Male Woman
Geography area	National
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2013
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1150
Data	
Database activity	Data collection completed

Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Validation of selection criteria ; Patients' demographics (age and sex) ; Pregnancy test for women of childbearing age ; Clinical data ; Co-morbidities and associated factors ; History of chronic C hepatitis ; Most recent biological data ; Most recent histological data ; Treatment with Pegasys® and Copegus® ; Date of permanent discontinuation of Pegasys® treatment and reason(s) ; Lifestyle and therapeutic recommendations, concomitant treatments ; Adverse events ; Date and reason of early study withdrawal ; Quality of life questionnaire (HQLQ).
Presence of a biobank	No
Procedures	
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only