

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
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Sign or acronym	ORPHEE
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22790
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General Aspects

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

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

Participation in projects, networks and consortia	No
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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 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