ANRS CO23 CUPILT - Cohort of Liver Transplant Patients with Hepatitis C Recurrence Treated with Direct Acting Antiviral Agent

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General

Identification

Detailed name	Cohort of Liver Transplant Patients with Hepatitis C Recurrence Treated with Direct Acting Antiviral Agent
Sign or acronym	ANRS CO23 CUPILT

General Aspects

Medical area	Biology Gastroenterology et hepatology Infectious diseases
Health determinants	Iatrogenic Medicine
Keywords	drug interactions, direct acting antivirals, liver transplant, HCV

Scientific investigator(s) (Contact)

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Unit	Joint Research Unit U785
Organization	Paul Brousse Hepatobiliary Centre

Collaborations

Funding

Funding status	Public
Details	ANRS, Inserm

Governance of the database

Sponsor(s) or organisation(s) responsible	Inserm-ANRS
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Service d'Hépatogastroentérologie, Hôpital Saint-Eloi, Montpellier
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Centre Hépato-Biliaire Paul Brousse
Organisation status	Public
Presence of scientific or	Yes

steering committees

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	Yes
Details	Performed at individual level

Database objective

Main objective	To investigate the efficacy, defined as obtaining a sustained virology response after 12 weeks of completing treatment, of direct acting agents (DAA) with or without peginterferon and/or ribavirin therapy, in liver transplant patients with Hepatitis C virus (HCV) infection recurrence following liver transplantation, regardless of genotype or response to previous treatment.
Inclusion criteria	? elderly subjects over 18 years old ? transplanted liver ? infected with HCV before transplantation ? presenting Hepatitis C virus (HCV) infection recurrence (regardless of genotype) with detectable HCV RNA at baseline ? received or receiving antiviral therapy with a direct antiviral agent or having completed treatment but still being monitored (within 48 weeks after completing treatment) ? member of a social security scheme ? signed consent form N.B.: Included ? multiple transplants ? treatment-naive or failed treatment patients, before and after transplantation, regardless of previous model

	? patients with HIV or HBV co-infection ? all stages of hepatic fibrosis
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
Gender	Male Woman
Geography area	International
Detail of the geography area	France and Belgium
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	10/2013
Date of last collection (YYYY or MM/YYYY)	06/2018
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	800
Data	
Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Year of birth; sex; details of ethnicity and skin colour; unresolved medical comorbidities at baseline; details regarding pre-transplantation; donor; transplantation; details regarding post-

	transplantation treatments and complications; height; weight; treatment tolerance; treatments (? immunosuppressants (collected up to 4 weeks following DAA treatment completion) ? antiretroviral treatment ? hematopoietic growth factors ? corrective action plans for adverse effects and Grade 3 serious adverse effects ? any other treatments deemed significant by the investigator)
Biological data (detail)	FBC; INR platelets; Albumin; TP; ALT; AST; GGT PAL; total bilirubin; RNA and HCV; residual immunosuppressive concentration; if HIV+: Viral load and CD4 count
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Blood cells isolated
Details of biobank content	Plasma and serum for DNA extraction and cell bank.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation Medicines consumption
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	Treatment duration and 48 weeks following treatment completion.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/pubmed-ANRSCO23
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge and Inserm?ANRS sponsor.
Access to aggregated data	Access on specific project only

Access to individual data

Access on specific project only