

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

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Last update : 06/29/2016 | Version : 1 | ID : 73116

## General

### Identification

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

### General Aspects

|              |  |
|--------------|--|
| Medical area | Biology<br>Gastroenterology et hepatology<br>Infectious diseases |
|--------------|--|

|                     |                        |
|---------------------|------------------------|
| Health determinants | Iatrogenic<br>Medicine |
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|----------|--|
| Keywords | drug interactions, direct acting antivirals, liver transplant, HCV |
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### Scientific investigator(s) (Contact)

|                      |  |
|----------------------|--|
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| Unit         | Joint Research Unit U785                                |
| Organization | Paul Brousse Hepatobiliary Centre                       |

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| Unit                 | Joint Research Unit U785                                |
| Organization         | Paul Brousse Hepatobiliary Centre                       |

|                |
|----------------|
| Collaborations |
| Funding        |

|                |        |
|----------------|--------|
| Funding status | Public |
|----------------|--------|

|         |              |
|---------|--------------|
| Details | ANRS, Inserm |
|---------|--------------|

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| 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 Hépto-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 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-naïve 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<br>Plasma<br>Blood cells isolated   |
| Details of biobank content  | Plasma and serum for DNA extraction and cell bank.  |
| Health parameters studied   | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services  |
| Care consumption (detail)   | Medical/paramedical consultation<br>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  | <a href="http://tinyurl.com/pubmed-ANRSCO23">http://tinyurl.com/pubmed-ANRSCO23</a>   |
| 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