HEPATHER - Therapeutic options for hepatitis B and C: a French nationwide cohort study

Head :Carrat Fabrice, Unité INSERM UMR-S 707: Épidémiologie, Systèmes d'Information, Modélisation Equipe : Epidémiologie des maladies infectieuses et modélisation
Pol Stanislas, U1016 Institut COCHIN- EMC - Régénération, ploïdie et senescence dans la pathophysiologie hépatique

Last update : 05/21/2012 | Version : 2 | ID : 3286

General

Identification

Detailed name	Therapeutic options for hepatitis B and C: a French nationwide cohort study
Sign or acronym	HEPATHER

General Aspects

Medical area	Gastroenterology et hepatology Infectious diseases
Health determinants	Medicine
Keywords	Therapeutics, Virology, Pathology and Physiopathology, Public health, antiviral HBV therapies, drug resistant mutants

Scientific investigator(s) (Contact)

Name of the director	Carrat
Surname	Fabrice
Address	INSERM UMR-S 707, Faculté de médecine Saint-Antoine, 27, rue Chaligny, PARIS CEDEX 12
Phone	+33 (0)1 44 73 84 58
Email	fabrice.carrat@u707.jussieu.fr
Unit	Unité INSERM UMR-S 707: Épidémiologie, Systèmes d'Information, Modélisation Equipe : Epidémiologie des maladies infectieuses et modélisation
Organization	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE -
Name of the director	Pol

Surname	Stanislas
Phone	+33 (0)1 58 41 30 00
Email	stanislas.pol@cch.aphp.fr
Unit	U1016 Institut COCHIN- EMC - Régénération, ploïdie et senescence dans la pathophysiologie hépatique
Organization	Assistance Publique des Hôpitaux de Paris

Collaborations

Funding

Funding status	Public
Details	ANR EQUIPEX des Investissements d'avenir, ANRS

Governance of the database

Sponsor(s) or organisation(s) responsible	AGENCE NATIONALE DE RECHERCHE SUR LE SIDA ET LES HÉPATITES VIRALES (ANRS)
Organisation status	Public
Sponsor(s) or organisation(s) responsible	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE - INSERM
Organisation status	Public

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 carried out as part of an interventional study	No
Additional information regarding sample selection.	The inclusion period will start en 2012 and will last 2 years. Each participing center wil aim to recruit as many as possible the patient population during a period of one year. In each center, inclusion

	capacities will be investigated from medical local database and number of daily medical visits and a weekly schedule of inclusions will be built and assessed in a feasibility period. Inclusion of consecutive patients will be favored. We anticipated an average of number of inclusion/ working day (WD) of 5 in each participing center (provisional number of clinical center: 30) and an accrual period of one year (250 WD).
Database objective	
Main objective	The HEPATHER project aims to set-up a cohort of patients with viral hepatitis B or C in order to improve management and care, givin the changing era of therapeutic options as news drugs come on the market. A major scientific and public-health challenge will be to improve quality of medical care in chronic hepatitis taking into account the different treatment options and host characteristics. The objectives of this cohort will be: - To describe the epidemiology of these chronic infection at a period when screening of viral infection and early diagnosis increase, and genetic and research of biomarkers of disease progression or treatment success are rapidly evolving; -To obtain original data on efficacy and safety of new hepatitis treatments in real-life, on a large size of patients, with a long term follow-up, allowing to estimate the public health impact of these treatments in terms of reduction of morbidity or mortality; - To study the relative effects of treatments to determine, at the level patient, which will be most likely to improve overall health and to limit emergence of variants and breakthrough; - To elaborate and compare cost-effectiveness strategies for the management and treatment of chronic HCV and HBV infections ; - To offer outstanding competency and ressources for the design of clinical trials on specific sub-population This project got an original governance including academic and regulatory institutions as well as pharmaceutical industries and patients associations
Inclusion criteria	HBV-positive patients - chronic hepatitis B defined by a positive HBs Ag for at least 6 months, with less than 50% of inactive carriers - acute hepatitis B defined as a recent appearance

	(<6 months) of detectable HBs Ag, with or without association with acute or chonic hepatitis D HCV-positive patients - chronic hepatitis C defined by the positivity for anti-HCV antibodies for at least 6 months, and positive HCV-RNA, - acute hepatitis B defined by the recent appearance of HCV RNA (<6 months) in patients with risk factors (with or without positives antibodies) - patients with cured hepatitis C defined by lond term radication, either treatment, either spontaneous, a positive anti-HCV antibodies associated to a negative RNA at two collection - 6 months interval time (this patients should represent less than 10% patients).
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	National
Detail of the geography area	30 clinical centers widespread in France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	- 15,000 patients / hépatite C c- 10,000 patients / hépatite B c
Data	
Database activity	Current data collection

Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Biological data (detail)	hepatitis followvirology
Administrative data (detail)	SNIIR-AM
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) Tissues DNA
Details of biobank content	Baseline visit: it is decided to collect blood (serum collection, plasma and white and red cell buffy coat collection), tissue (liver biopsies samples collected retrospectively or prospectively during surgical intervention in patients with cirrhosis or/and hepatocellular carcinoma), urine and feces.follow-up: Sampling follow-up is not systematic but will be motivated by a specific research project or a medical evant such as disease progression or the initiation of a new treatment. Ex: blood and urine when a treatment for hepatitis is initiated Centralized blood collections will be interfaced with the BIOBANQUES infrastructure of French human and microorganisms biobanks.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Retrospective and prospective data will be collected

	with an anticipated follow-up of 10 years to allow analyzing the epidemiology, treatment hisory, genetic and environmental risk factors of disease progression, interactions between these factors and various individual and public health outcomes.When a eligible patient arrives at the assessment he/she will move through a series of assessment involving questionnaires, measurements, and blood/urine/feces sampling. During the visit, detailed demographics, clinical, biological and virological data will be collected. In each participing center, the existing database (if any) and the capacities of extracting and importing data from the database into the dedicated information system will be investigated. It is expected that 80% of historical patient data in the cohort would be imported from existing medical files.The general approach of follow-up will be to combine systematic follow-up visits for particular events (such as clinical event or initiation of therapy) with using a variety of different national administrative databases and sources to ascertain death and other health related information, using support of the PLASTICO plateforme.The devoted information system will allow patient to self report on various items and most notably QoL studies.
Participant monitoring	Yes
Details on monitoring of participants	We anticipated a follow-up of 10 years
Links to administrative sources	Yes
Linked administrative sources (detail)	An interrogation of the french "repertoire national d'identification des personnes physiques (RNIPP)" in addition to the database of "Centre d'épidémiologie des causes médicales de décès (CépiDC)" would allow to access the vital status of enrolled patient and cause of death (if any). The possibility of an interrogation of the "Système national d'information inter régimes de l'assurance maladie (SNIIR-AM)", which includes data from the national health insurance système including hospitalization and causes of hospitalization, is under assesment.

Promotion and access

Promotion

Link to the document	https://www.ncbi.nlm.nih.gov/pubmed/?term=(hepather+NOT+heather)+AND+Carrat+F%5BAuthor%5D

Access	
Terms of data access (charter for data provision, format of data, availability delay)	Accessibility of the database will be determined case by case by the executive committee in agreement with the scientific committee. The intellectual property and contractual issues will be managed by Inserm Transfert. Special attention will be paid on confidentiality, ethical issues and on the use of the biobank to yield the greatest scientific value to the community and avoid depletion of this finite ressource. The proposal will be examined by the executive committee. The committee will assist academic and private researchers with queries and will advise on data quality, study design and data analysis if necessary. The committee will ensure the coherence with other projects. The executive committee will evaluate methodological aspects and scientific relevance based on reports from the scientific committee. Independent external experts will provide advice on decisions relative to access rights, for example on issues related to the access on one industrial to data linked to the product of another industrial. It will prioritize projects. In preparation for data sharing, much attention will be paid to the wording within subject consent documents. The executive committee will establish policies to facilitate data sharing and to provide a mechanism for tracking publications related to and resulting from Hepather data. Moreover the executive committee will monitor contributions of the ancillary studies to the community and will require results to be incorporated into a resource database for use by other researchers. The flexibility of web-based database will also facilitate the addition of new questionnaires for ancillary studies.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only