NEPHROVIR 2 - CHILDHOOD NEPHROTIC SYNDROME (2)

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Last update : 08/06/2014 | Version : 1 | ID : 5128

General

Identification

Detailed name	CHILDHOOD NEPHROTIC SYNDROME (2)
Sign or acronym	NEPHROVIR 2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL

General Aspects

Medical area	Urology, andrology and nephrology
Others (details)	Nephrotic syndrome
Keywords	Analysis, immuno-virological status, idiopathic, corticosteroids, B lymphocytes, health episodes, proteinuria, glucocorticoids, after-effect, immunosuppressants, Epstein Barr Virus (EBV), impact, progression, incidence, recurrence, complications

Scientific investigator(s) (Contact)

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Unit	INSERM UMR699
Organization	INSERM -

Collaborations

Funding	
Funding status	Public
Details	Direction générale de la santé DGS- Le programme hospitalier de recherche clinique PHRC (nephrovir-2) DHOS
Governance of the database	
Sponsor(s) or organisation(s) responsible	AP-HP
Organisation status	Public
Sponsor(s) or organisation(s) responsible	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.	Inclusion method: Prospective Other bodies active in creating this cohort: CHU, CHG
Database objective	
Main objective	To analyse the immuno-virological status of patients concerning Epstein Barr Virus (EBV) during the first manifestation of idiopathic nephrotic syndrome, and its impact on steroid therapy progression. A further study is proposed for the phenotypic characterisation and analysis of B lymphocytes in patients with relation to the EBV cycle.
Inclusion criteria	Children between 6 months and 15 years old, living in the Ile de France area, with first manifestation of

	idiopathic nephrotic syndrome defined as proteinuria higher than 50 mg/kg/day or proteinuria/creatinine higher than 0.25 g/mmol and hypoalbuminemia less than 30 g/L. Group 2: negative serology for hepatitis B and hepatitis C virus, no decrease in C3 component. Group 3: samples for hepatitis B virus, hepatitis C virus and C3 complement component serology. Children not living in Ile de France at time of first manifestation are excluded.
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Île-de-France
Detail of the geography area	Ile de France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	12/2007
Date of last collection (YYYY or MM/YYYY)	06/2020
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	350
Data	
Database activity	Current data collection

Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Presence of a biobank	Yes
Contents of biobank	Whole blood Plasma DNA
Details of biobank content	Plasma bank, DNA bank, cell bank
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Blood samples (2.5 mL EDTA and 2 tubes of 2.4 mL ACD) collected for study during routine laboratory tests are sent to the Clinical Investigation Centre (CIC) at the Hôpital Robert Debré: The EDTA tube will be immediately forwarded to the pharmacology laboratory for plasma collection and DNA extraction before aliquoting and freezing with further genetic study. Self-administered questionnaire: From paper questionnaire (Manual input)
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 10 years
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by industrial teams. Contractual access. Data may not be used by industrial teams.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only