SAM - Severe Drug Allergy Physiopathology and Characterisation of Novel Diagnostic and Therapeutic Targets

Head :Nicolas Jean-François, Equipe 14 Inserm U1111- CIRI "Immunologie de l'allergie cutanée et vaccination"
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General

Identification

Detailed name	Severe Drug Allergy Physiopathology and Characterisation of Novel Diagnostic and Therapeutic Targets
Sign or acronym	SAM
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--

General Aspects

Medical area	Study of allergies
Health determinants	Genetic

Scientific investigator(s) (Contact)

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Surname	Jean-François
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Unit	Equipe 14 Inserm U1111- CIRI "Immunologie de l'allergie cutanée et vaccination"
Organization	INSERM - Institut National de la Santé et de la Recherche
Name of the director	Berard

Surname	Frédéric
Collaborations	
Funding	
Funding status	Mixed
Details	AO HCL Action incitative 2009 INSERM/DHOS 2009
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
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.	Prospective. All patients who attended CCR2A and agreed to be included in cohort. No randomisation or selection.
Database objective	
Main objective	To improve pathophysiological understanding of cutaneous Adverse Drug Reaction (cADRs) by clarifying the number and functional status of T lymphocytes (LT) CD8 + CTLs specific to medication. We wish to: i) confirm the involvement of CD8+ cells for different diseases; ii) understand why the same cell (CD8+) is responsible for different clinical forms of severity.
Inclusion criteria	Patient presenting with maculopapular rash (MPR), Drug Hypersensitivity Syndrome (DRESS) or Lyell's Syndrome (toxic epidermal necrolysis) (SJS/TEN)

	caused by medication, diagnosed by referring physicians in the Rhône-Alpes Auvergne Centre de Compétences (CCR2A)
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Auvergne Rhône-Alpes
Detail of the geography area	Rhône-Alpes-Auvergne
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	102
Data	
Database activity	Current data collection
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures Medical registration
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?)

	Tissues Others
Details of biobank content	Blood sample (30 mL heparin tube), Two skin biopsies (3 mm in diameter), one for damaged skin and one for healthy skin
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	All cohort samples were collected by Allergobiotec (Headed up by Dr. Aurore Rozieres, INSERM U1111-CIRI/HCL).
Participant monitoring	Yes
Details on monitoring of participants	Systematic visit 3 months following reaction. Other follow-ups (6 months and 9 months) may be scheduled depending on the patient's condition and severity of reaction. A visit at 1 year is also systematic.
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data from this cohort are accessible through scientific publications. If other researchers wish to access this data, a request must be made and data will be made available according to good clinical practice. Filtered "access request". No "open access".
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only