

CRYOSTEM - Cryoconservation during allogeneic hematopoietic Stem cell transplantation

Head : Peffault De Latour Régis, Service d'hématologie / Greffe
Calmels Boris, Centre de thérapie cellulaire
Fontenille Claire, Centre de thérapie cellulaire
Robert Emilie, Centre de Thérapie Cellulaire

Last update : 02/17/2020 | Version : 2 | ID : 3107

General

Identification

Detailed name Cryoconservation during allogeneic hematopoietic Stem cell transplantation

Sign or acronym CRYOSTEM

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CPP Sud-Méditerranée (17/02/2012) : AC-2011-1420, CCTIRS (09/02/2012) : 11-710bis, CNIL

General Aspects

Medical area Cancer research
Hematology
Immunology
Infectious diseases
Pediatrics

Health determinants Iatrogenic

Keywords Graft-versus-host-disease, GvHD, Allogeneic Hematopoietic Stem Cell Transplantation, HSCT, Biobanking network, Complications

Scientific investigator(s) (Contact)

Name of the director Peffault De Latour

Surname Régis

Address 1, avenue Claude Vellefaux 75010 PARIS

Phone + 33 (0)1 42 38 50 73

Email regis.peffaultdelatour@sls.aphp.fr

Unit	Service d'hématologie / Greffe
Organization	Hôpital Saint Louis
Name of the director	Calmels
Surname	Boris
Address	232, boulevard Sainte Marguerite 13009 MARSEILLE
Phone	+ 33 (0)4 91 22 34 41
Email	calmelsb@ipc.unicancer.fr
Unit	Centre de thérapie cellulaire
Organization	Institut Paoli Calmettes

Name of the director	Fontenille
Surname	Claire
Address	232, boulevard Sainte Marguerite 13009 MARSEILLE
Phone	+ 33 (0)4 91 22 34 37
Email	claire.fontenille@cryostem.org
Unit	Centre de thérapie cellulaire
Organization	Institut Paoli Calmettes

Name of the director	Robert
Surname	Emilie
Address	232, bd Sainte Marguerite 13009 Marseille
Phone	+ 33 (0)4 91 22 34 37
Email	emilie.robert@cryostem.org
Unit	Centre de Thérapie Cellulaire
Organization	Institut Paoli Calmettes

Collaborations

Participation in projects, networks and consortia	Yes
---------------------------------------------------	-----

Funding

Funding status	Mixed
Details	ANR "Investissements d'avenir -Grand emprunt"
Governance of the database	
Sponsor(s) or organisation(s) responsible	CRYOSTEM
Organisation status	Private
Presence of scientific or steering committees	Yes
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:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	<p>The goal of CryoStem is to create a national, multicenter, prospective, longitudinal, standardized HSCT human-sample collection (derived from adult and pediatric patients) with the purpose of enabling better characterization and prediction of HSCT complications occurrence and outcome, including GvHD.</p> <p>CryoStem has generated a French network involving all the French transplant units, adult and pediatric and 28 Biological Resources Centres. Only in a network such as this may the full potential be realized of having concrete and effective interactions between scientists with top knowledge in specific areas and physicians. CryoStem fosters interactions among internationally recognized experts in advanced biotechnology</p>

(genomics, transcriptomics, proteomics, and flow cytometry).
Altogether, CryoStem provides a structured approach for a range of different research activities, bringing together leading-edge researchers who can access documented biological (CryoStem) and clinical (ProMISe) samples from transplanted patients in order to better characterize and predict HSCT complications.

Inclusion criteria

Any patient suffering from a severe blood disease or blood cancer (leukemia, lymphoma, aplastic anemia...) justifying a first HSCT in one of the transplant units of CRYOSTEM network.

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)
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

Pathology

III - Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Gender

Male
Woman

Geography area

National

Detail of the geography area

Metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2012

Date of last collection (YYYY or MM/YYYY)

2019

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of individuals 5 756 patients and 2 375 donors as of August, 31 2019

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 transplant type and date / relapse / graft failure / second transplant / stages and corticoreistance for the acute GvHD / type, classification and evolution of the chronic GvHD

Biological data (detail) Blood samples

Presence of a biobank Yes

Contents of biobank Plasma
Blood cells isolated
Others

Details of biobank content Viable mononuclear cells, plasma, and dried cell pellets

Health parameters studied Health event/morbidity
Health event/mortality

Procedures

Data collection method Data are collected via a unique document filled in as the time of blood samples by the transplant units staff in charge of the patient medical follow-up.

Quality procedure(s) used Sampling and sending / blood samples reception and processing

Participant monitoring Yes

Details on monitoring of participants Duration of CryoStem : 7 years (inclusion : 6 years)

Links to administrative sources No

Promotion and access

Promotion

Description	The first publications have been submitted during the summer 2019.
-------------	--------------------------------------------------------------------

Other information	The embargo on the CRYOSTEM samples has ended on 2015/04/15. Since 2015, and as of August, 31 2019, almost 7 000 samples have been provided to 10 research projects on GvHD and HSCT complications.
-------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Access

Presence of document that lists variables and coding procedures	Yes
-----------------------------------------------------------------	-----

Terms of data access (charter for data provision, format of data, availability delay)	<p>Any investigator selected by CRYOSTEM Scientific Committee commits himself to respect the general terms of the current call of projects to access the collection biological resources.</p> <p>The investigator could access to demographical and clinical information, extracted from the European register of the EBMT (European Society for Blood and Marrow Transplantation), provided via an Excel file made anonymous.</p> <p>Once selected, CRYOSTEM project managers schedule interviews with the investigators in order to identify and select the samples of interest. The delay of provision depend on the number of the samples waited for.</p>
---------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Access to aggregated data	Access on specific project only
---------------------------	---------------------------------

Access to individual data	Access on specific project only
---------------------------	---------------------------------