

FROG-ICU - Cohort of Patients Admitted to Intensive Care for Serious Illnesses: Study on Mortality Risk Factors Up to One Year

Head :Mebazaa Alexandre, UMR-S 942 Inserm
Gerard Sophie, Lariboisière Clinical Research Unit

Last update : 06/20/2016 | Version : 1 | ID : 73036

General

Identification

Detailed name Cohort of Patients Admitted to Intensive Care for Serious Illnesses: Study on Mortality Risk Factors Up to One Year

Sign or acronym FROG-ICU

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CCTIRS ref. 11134 on 10/03/11 CNIL authorisation 30/06/11 under no. 911169 CPP 15/03/11 under ref. 2011/05NI; Clinical Trials.gov NCT01367093. Biological collection declaration at the ministry 21/06/12.

General Aspects

Medical area Anesthesiology ? Intensive care

Health determinants Healthcare system and access to health care services
Iatrogenic
Lifestyle and behavior

Keywords intensive care, SF36, serious illness, mortality, morbidity, quality of life

Scientific investigator(s) (Contact)

Name of the director Mebazaa
Surname Alexandre
Phone +33 (0)1 53 21 67 60
Email alexandre.mebazaa@lrb.aphp.fr
Unit UMR-S 942 Inserm
Organization Paris Public Hospitals

Name of the director	Gerard
Surname	Sophie
Phone	+33 (0) 1 40 45 49 85
Email	sophie.gerard@lrb.aphp.fr
Unit	Lariboisière Clinical Research Unit
Organization	AP-HP

Collaborations

Funding

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

Details	AP-HP (Paris Public Hospitals)
---------	--------------------------------

Governance of the database

Sponsor(s) or organisation(s) responsible	Assistance Publique - Hôpitaux de Paris
---	---

Organisation status	Public
---------------------	--------

Presence of scientific or steering committees	Yes
---	-----

Additional contact

Main features

Type of database	Study databases
------------------	-----------------

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:	Another treatment or procedure
---	--------------------------------

Additional information regarding sample selection.	21 centres throughout France and Belgium.
--	---

Database objective

Main objective	This study aims to identify the risk factors of
----------------	---

mortality within a cohort of patients during the year following discharge from the intensive care unit.

Inclusion criteria	Adult patients admitted to the ICU. Patients must be intubated for at least 24 hrs or treated with an inotropic agent.
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	France and Belgium
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2011
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2,136
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Declarative data (detail)	Paper self-questionnaire Face to face interview
Details of collected declarative data	Quality of life analysis (SF36)

Presence of a biobank	Yes
Details of biobank content	Yes; managed by the Lariboisière CRB (Centre de ressources biologiques [biological resource centre])

Health parameters studied	Health event/mortality Quality of life/health perception
---------------------------	---

Procedures

Data collection method	Data collected in an eCRF designed by the St. Louis DBIM (data and biostatistics unit), monitoring carried out by the Lariboisière Clinical Research unit; queries published and resolved.
------------------------	--

Participant monitoring	Yes
------------------------	-----

Details on monitoring of participants	Follow-up at 3/6/12 months
---------------------------------------	----------------------------

Links to administrative sources	No
---------------------------------	----

Promotion and access

Promotion

Link to the document	Legrand M, Januzzi JL Jr, Mebazaa A. Critical research on biomarkers: what's new? Intensive Care Med. 2013 Oct;39(10):1824-8. doi: 10.1007/s00134-013-3008-7. Epub 2013 Jul 5.
----------------------	--

Link to the document	http://tinyurl.com/PUBMED-FROG-ICU
----------------------	---

Access

Terms of data access (charter for data provision, format of data, availability delay)	Access to database through login and code for site users and coordinating team (DBIM, URC, Mebazaa team).
---	---

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

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