

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

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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)

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| Unit | Lariboisière Clinical Research Unit |
| Organization | AP-HP |

Collaborations

Funding

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|----------------|--------|
| 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

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.

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| 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) |

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

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| Health parameters studied | Health event/mortality Quality of life/health perception |
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Procedures

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| 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. |
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| Participant monitoring | Yes |
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| Details on monitoring of participants | Follow-up at 3/6/12 months |
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|---------------------------------|----|
| Links to administrative sources | No |
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Promotion and access

Promotion

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

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| 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). |
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| Access to aggregated data | Access on specific project only |
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| Access to individual data | Access on specific project only |
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