ISRCTN36541230 https://doi.org/10.1186/ISRCTN36541230

Cardiac arrest registry of the Greater Paris area

Submission date
05/01/2017

Recruitment status
Recruiting

Registration date
16/01/2017

Overall study status
Ongoing

Last Edited
15/01/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Sudden cardiac arrest is a condition where the heart suddenly and unexpectedly stops beating, which usually causes death if not treated within minutes (sudden cardiac death). In spite of advances in treatment, it remains a frequent and often fatal disease, with highly different survival rates between studies and countries. The aim of this study is to create a registry (database) of patients who have an out-of-hospital cardiac arrest in Paris or its suburbs (Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne).

Who can participate?
Patients aged over 18 who have an out-of-hospital cardiac arrest in Paris or its suburbs (Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne) and are treated by the Emergency Medical Service (EMS)

What does the study involve?
Patient data is collected, including their demographic characteristics and the location of their arrest. Information is also collected about the care patients receive before admission to hospital, such as response time (the delay between call and arrival of EMS), presence of bystander, bystander cardio-pulmonary resuscitation (CPR) before EMS arrival, presence of shockable heart rhythm, attempted defibrillation during resuscitation, dose of epinephrine delivered by EMS, and survival until admission. For every hospitalized patient, the hospitalization report is recorded, including past medical history, tests, coronary angiogram, and death or discharge from hospital.

What are the possible benefits and risks of participating?
As the study only involves collecting data there are no benefits or risks of participating.

Where is the study run from?
Hospitals in Paris and its suburbs (Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne)

When is the study starting and how long is it expected to run for?
May 2011 to May 2041

Who is funding the study?
1. Institut National de la Santé et de la Recherche Médicale (France)
2. Université Paris Descartes (France)

3. Fédération Française de Cardiologie (France)
4. Société Française de Cardiologie (France)
5. Fondation Coeur et Artères (France)
6. Global Heart Watch (France)
7. Fondation pour la Recherche Médicale (France)

Who is the main contact?
1. Prof. Xavier Jouven
2. Dr Wulfran Bougouin

Contact information

Type(s)
Scientific

Contact name
Prof Xavier Jouven

Contact details
INSERM U970, Team 4
56 rue Leblanc
Paris
France
75015

Type(s)
Scientific

Contact name
Dr Wulfran Bougouin

Contact details
INSERM U970, Team 4
56 rue Leblanc
Paris
France
75015

Additional identifiers

Protocol serial number
-

Study information

Scientific Title
Out-of-hospital cardiac arrest registry of the Paris Sudden Death Expertise Centre, France

Acronym

SDEC registry

Study objectives
In spite of therapeutic advances, sudden cardiac death (SCD) remains a frequent and often fatal disease, with highly different survival rates between studies and countries. Knowledge about the extent of this disease is crucial in order to match research themes with public health needs.

In a recent meta-analysis, Sasson et al. reported a survival rate to hospital discharge after SCD between 6 and 8%. However, the French emergency medical system (EMS) differs significantly from the North American EMS, with early medicalization of patients. The impact of this marked specificity is discussed. To the best of our knowledge, prognosis of SCD is not documented in the French EMS system.

During OHCA patients' hospitalization, percutaneous coronary intervention (PCI) and therapeutic hypothermia (TH) have been proposed to improve the prognosis of SCD. However, despite their inclusion in guidelines, the extent of these therapies in clinical practice is not known, and available data are derived from trials involving intensive care units highly aware of the benefits of these therapies, or from declarative surveys.

Considering the lack of broad epidemiological data, a population-based registry has been developed with multiple sources, serving exhaustively a large population in Paris and its suburbs, representing more than 10% of the overall French population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. CCTIRS (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé), 07/06/2012, ref: 12-336
2. CNIL (Commission Nationale de l'Informatique et des Libertés), 18/09/2012, ref: 912309

Primary study design
Observational

Study design
Prospective population-based observational registry

Study type(s)
Other

Health condition(s) or problem(s) studied
Out-of-hospital sudden cardiac death

Interventions
The Sudden Death Expertise Center (SDEC) Registry is a population-based registry, concerning Paris and its suburbs (Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne), including a residential population of approximately 6.6 million and covering 762 km2 (294 square miles).

According to definitions from recent guidelines, every case of out-of-hospital Sudden Cardiac Death (SCD), defined as unexpected death without obvious extra-cardiac cause, occurring in the area of interest, with age over 18 years, was included in SDEC registry, from the 15/05/2011, for

at least 20 years. Exclusion criteria were patients aged under 18 years old, SCD occurring outside the area of interest, prior terminal condition (such as metastatic malignancy), or obvious non-cardiac cause according to Utstein templates (trauma, submersion, respiratory, etc).

To ensure completeness of collection, the SDEC Registry was derived from an intensive and prospective epidemiologic case-finding. Combining passive and active attitudes warranted the most extensive collection of cases of SCD, significantly superior to passive detection of cases alone. In addition, an individual review of each case ensured specificity, and avoided the overestimation often experienced in retrospective collection.

Utstein templates for patient data collection were followed. General data included demographic characteristics and location of arrest (street address, residential or public place). Data recorded about pre-hospital care included response time (defined by the delay between call and arrival of EMS), presence of bystander, bystander cardio-pulmonary resuscitation (CPR) before EMS arrival, presence of shockable rhythm before advanced life support, defibrillation attempt during resuscitation, deliverance and dose of epinephrine (total dose delivered by EMS during Advance Life Support), and survival until admission.

For every hospitalized patient, the hospitalization report was recorded, including past medical history, biological tests, therapeutic hypothermia, coronary angiogram, death or discharge from hospital, and neurological status at discharge (according to Cerebral Performance Category [CPC] score, considering a CPC score of 1 or 2 as a favorable outcome). Two investigators reviewed each record for data completion and validity.

Intervention Type
Other

Primary outcome(s)
Survival at hospital discharge, assessed using hospitalization reports

Key secondary outcome(s)
1. Survival at ICU discharge
2. 7 days survival
3. 30 days survival
4. Neurological status at discharge, according to Cerebral Performance Category (CPC) score, considering a CPC score of 1 or 2 as a favorable outcome
5. One-year survival
6. Long-term survival
7. Cause-of-death analysis

Completion date
15/05/2041

Eligibility

Key inclusion criteria
1. Out-of-hospital SCD (defined as unexpected death without obvious extra-cardiac cause) occurring in Paris or its suburbs (Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne)
3. Age over 18 years
4. Treated by the Emergency Medical Service

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients aged under 18 years old
2. Cardiac arrest occurring outside the area of interest
3. Prior terminal condition (such as metastatic malignancy)
4. Obvious non-cardiac cause according to Utstein templates (trauma, submersion, respiratory, etc)

Date of first enrolment
16/05/2011

Date of final enrolment
15/05/2041

Locations

Countries of recruitment
France

Study participating centre
SAMU 93
France
93000

Study participating centre
Georges Pompidou European Hospital
Medical ICU
France
75015

Study participating centre

Béclère Hospital
Cardiology Department
France
92140

Study participating centre
Raymond Poincare Hospital
Medical ICU
France
92380

Study participating centre
Bichat Hospital
Cardiology Department
France
75018

Study participating centre
Saint Louis Hospital
Medical ICU
France
75010

Study participating centre
Bicêtre Hospital
Surgical ICU
France
94270

Study participating centre
PARCC, INSERM U970
France
75015

Study participating centre
Georges Pompidou European Hospital
Cardiology Department
France
75015

Study participating centre
Necker Hospital
Medical ICU
France
75015

Study participating centre
SAMU 75
France
75015

Study participating centre
Saint Joseph Hospital
Medical ICU
France
75014

Study participating centre
Cochin Hospital
Medical ICU
France
75014

Study participating centre
Foch Hospital
Medical ICU
France
92151

Study participating centre
Montreuil Hospital
Cardiology Department
France
93100

Study participating centre

Pitié Salpétrière Hospital
Medical ICU
France
75013

Study participating centre
Avicenne Hospital
Medical-Surgical Intensive Care Unit
France
93000

Study participating centre
SAMU 92
France
92380

Study participating centre
Delafontaine Hospital
ICU
France
93200

Study participating centre
Montreuil Hospital
ICU
France
93100

Study participating centre
Lariboisière Hospital
Medical ICU
France
75475

Study participating centre
Mondor Hospital
Surgical ICU
France
94010

Study participating centre
Paris Fire Brigade
France
75000

Study participating centre
Louis Mourier Hospital
Medical ICU
France
92700

Study participating centre
Cochin Hospital
Cardiology Department
France
75014

Study participating centre
Mondor Hospital
Cardiology Department
France
94010

Study participating centre
Ambroise Paré Hospital
Cardiology Department
France
92100

Study participating centre
Cochin Hospital
Emergency Department
France
75014

Study participating centre

Tenon Hospital
Medical ICU
France
75020

Study participating centre
Montfermeil Hospital
ICU
France
93370

Study participating centre
Pitié Salpétrière Hospital
Cardiology Department
France
75013

Study participating centre
Saint Antoine Hospital
Medical ICU
France
75012

Study participating centre
Lariboisière Hospital
Cardiology Department
France
75475

Study participating centre
Saint Louis Hospital
Surgical ICU
France
75010

Study participating centre

Georges Pompidou European Hospital
Surgical ICU
France
75015

Study participating centre
Pitié Salpétrière Hospital
Surgical ICU
France
75013

Study participating centre
SAMU 94
France
94010

Study participating centre
Institute of Legal Medicine
France
75012

Study participating centre
Necker Hospital
Department of Pediatric Cardiology
France
75015

Study participating centre
Mondor Hospital
Medical ICU
France
94010

Study participating centre
Bicêtre Hospital
Medical ICU
France
94270

Study participating centre
Centre cardiologique du Nord
Cardiology Department
France
93200

Study participating centre
Pitié Salpétrière Hospital
Neuropathology Department
France
75012

Study participating centre
Robert Ballanger Hospital
ICU
France
93600

Study participating centre
Bichat Hospital
Medical ICU
France
75018

Study participating centre
Ambroise Paré Hospital
Medical ICU
France
92100

Study participating centre
Montfermeil Hospital
Cardiology Department
France
93370

Study participating centre

Pitié Salpétrière Hospital
Medical Intensive Care Unit and Respiratory Division
France
75013

Sponsor information

Organisation
INSERM U970, Team 4

ROR
https://ror.org/02vjkv261

Funder(s)

Funder type
University/education

Funder Name
Institut National de la Santé et de la Recherche Médicale

Alternative Name(s)
National Institute of Health and Medical Research, Institut national de la sante et de la recherche medical, French National Institute for Health and Medical Research, French National Institute of Health & Medical Research, Institut national de la santé et de la recherche médicale (Inserm), Inserm

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
France

Funder Name
Université Paris Descartes

Alternative Name(s)
Paris Descartes University, Universität Paris Descartes, Universidad Paris Descartes

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
France

Funder Name
Fédération Française de Cardiologie

Alternative Name(s)
French Federation of Cardiology, fedecardio, FFC

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
France

Funder Name
Société Française de Cardiologie

Alternative Name(s)
French Society of Cardiology, SFC

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
France

Funder Name
Fondation Coeur et Artères

Funder Name
Global Heart Watch

Funder Name
Fondation pour la Recherche Médicale

Alternative Name(s)
Foundation for Medical Research, The Fondation pour la Recherche Médicale FRM, The Fondation pour la Recherche Médicale, frm_officiel, FRM

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No
Results article	results	01/06/2014		Yes	No
Results article	results	07/11/2016		Yes	No
Results article	results	06/12/2016		Yes	No
Results article	results	20/12/2016		Yes	No
Results article	results	01/01/2017		Yes	No