

# Cardiac arrest registry of the Greater Paris area

<b>Submission date</b> 05/01/2017	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/01/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

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### Type(s)

Scientific

### Contact name

Dr Wulfran Bougouin

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

-

## 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

**Study design**

Prospective population-based observational registry

**Primary study design**

Observational

**Secondary study design**

Epidemiological study

**Study setting(s)**

Other

**Study type(s)**

Other

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **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 km<sup>2</sup> (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 measure**

Survival at hospital discharge, assessed using hospitalization reports

## **Secondary outcome measures**

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

**Overall study start date**

16/05/2011

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

3000 per year

**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 Salpêtrière 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 Salpêtrière 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 Salpêtrière 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 Salpêtrière 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 Salpêtrière Hospital**  
Medical Intensive Care Unit and Respiratory Division  
France  
75013

## **Sponsor information**

**Organisation**  
INSERM U970, Team 4

**Sponsor details**  
56 Rue Leblanc  
Paris  
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75015

**Sponsor type**  
University/education

**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)**

French National Institute for Health and Medical Research, French National Institute of Health & Medical Research, National Institute of Health and Medical Research, 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, FRM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

France

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/01/2026

## 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?
<a href="#">Results article</a>	results	01/11/2011		Yes	No
<a href="#">Results article</a>	results	01/06/2014		Yes	No
<a href="#">Results article</a>	results	07/11/2016		Yes	No
<a href="#">Results article</a>	results	06/12/2016		Yes	No
<a href="#">Results article</a>	results	20/12/2016		Yes	No
<a href="#">Results article</a>	results	01/01/2017		Yes	No