## Cardiac arrest registry of the Greater Paris area

Submission date	<b>Recruitment status</b> Recruiting	<ul><li>Prospectively registered</li></ul>	
05/01/2017		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
16/01/2017	Ongoing	[X] Results	
<b>Last Edited</b> 15/01/2025	<b>Condition category</b> Circulatory System	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

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## Additional identifiers

#### Protocol serial number

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## 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

#### 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

#### 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

#### 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

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

#### 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

#### 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

#### 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, 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**

#### **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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes