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# Sudden cardiac death in Denmark

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| **Submission date**<br>03/11/2016 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>13/12/2016 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/02/2017 | **Condition category**<br>Circulatory System | |

## Plain English summary of protocol

Background and study aims
Sudden and unexpected death caused by cardiac (heart) disease, also known as sudden cardiac death (SCD), is among the most common causes of death across all age groups. A deeper understanding of SCD has major clinical consequences, both in terms of the ability to better identify people at risk of SCD and through developing strategies to prevent SCD. Information on frequency, causes of and risk factors for SCD in the general population is missing. Previous studies on causes and occurrence of SCD has mainly been based on findings in one forensic department or a region of a country with data almost exclusively being obtained from people who have been autopsied. As autopsy is far from always conducted, these results do not necessarily apply to the general population. The aim of the study is to examine the occurrence, causes of and risk factors for SCD in a nationwide and unselected setting in Denmark between 2000-2014 by reviewing records.

Who can participate?
All registered deaths in Denmark of people aged between 1-25 years (between 2000-2006), 1-49 years (between 2007-2014) and of any age (2010 or later).

What does the study involve?
Danish death certificates are used to identify cases of sudden and unexpected deaths. All 77,767 death certificates are read independently by two phycisians to identify cases of sudden and unexpected death. Cases of sudden death due to cardiac causes (SCD) are subsequently identified using information from nationwide Danish registries on medical history and cause of death, and autopsy reports together with access to discharge summaries and in selected cases medical records. Cause of death and risk factors for SCD is identified using data from autopsy reports and the nationwide Danish registries.

What are the possible benefits and risks of participating?
There are no benefits or risks to participants.

Where is the study run from?
University Hospital of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
September 2014 to December 2015

Who is funding the study?
1. The John and Birthe Meyer Foundation (Denmark)
2. The Novo Nordisk Foundation (Denmark)

Who is the main contact?
Dr Jacob Tfelt-Hansen

# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Protocol serial number
H-KF-272484

# Study information

### Scientific Title
Burden of and risk factors for sudden cardiac death in Denmark

### Study objectives
Information from unselected populations on incidence and causes of and risk factors for sudden cardiac death (SCD) is missing. A deeper understanding of the epidemiology of SCD has major clinical implications, both in terms of the ability to better identify persons at risk for SCD and develop strategies to prevent SCD. Therefore, the aim of this nationwide and unselected study is to examine incidence and causes of and risk factors for SCD among 77,767 deaths in Denmark in 2000-2014.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

1. The Committees on Health Research Ethics for the Capital Region of Denmark, 11/08/2005, ref: KF-01 272484 (extended 08/10/2010)
2. The Danish Data Protection Agency, 11/05/2005, ref: 2011-41-5767 (extended 15/01/2016)

## Primary study design
Observational

## Study design
Retrospective epidemiological register study

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Sudden cardiac death

## Interventions
This is a nationwide and unselected study of 77,767 deaths in Denmark in 2000-2014. Persons aged 1-35 years are included in 2000-2006, persons aged 1-49 years in 2007-2014, and persons of all ages in 2010. This study is a retrospective, register-based study using death certificates as a screening tool for identification of sudden deaths. Danish death certificates can only be issued by a medical doctor and are informative and valid for identification of sudden unexpected deaths as they have a supplemental information field. This field includes a description of the circumstances leading to death including information on previous medical conditions, and often information from interviews with eyewitnesses, family members, and the patient's general practitioner. To identify cases of sudden and unexpected death, all death certificates issued for the 77,767 deaths in Denmark in 2000-2014 were reviewed independently by two physicians. In cases of disagreement, the two investigators reevaluated the death certificate together to reach a consensus.

Identification of victims of sudden cardiac death is subsequently performed using national Danish registries, autopsy reports, and access to discharge summaries and in selected cases medical records. Information from the above mentioned sources was subsequently used to describe incidence and causes of and risk factors for sudden cardiac death.

For the purpose of this study, sudden death has been defined as a sudden, natural, unexpected death; in witnessed cases, as an acute change in cardiovascular status with time to death being <1 hour and, in unwitnessed cases, as a person last seen alive and functioning normally <24 hours before being found death. Sudden cardiac death in autopsied cases is defined as a sudden death of unknown or cardiac cause and in non-autopsied cases as a sudden death presumed to be of cardiac origin after review of all available information.

Death certificates and information from the Danish registries are obtained from the Danish National Board of Health. Autopsy reports were obtained from local hospitals and the three Danish Departments of Forensic Medicine. Discharge summaries and medical records are obtained from local hospitals.

## Intervention Type
Other

### Primary outcome(s)
1. Incidence of sudden cardiac death in the general population is calculated based on information collected from death certificates, Danish registries, autopsy reports, discharge summaries, and medical records throughout the study period
2. Causes of sudden cardiac death in the general population is identified based on information collected from death certificates, Danish registries, autopsy reports, discharge summaries, and medical records throughout the study period

### Key secondary outcome(s)
1. Information from autopsies (including autopsy rates, toxicology, and histopathology) is collected from autopsy reports throughout the study period
2. Information on clinical characteristics (including age, gender, comorbidities, and symptoms prior to death) is collected from Danish registries, autopsy reports, and medical records throughout the study period
3. Information on circumstances of cardiac arrest (including information on place of death, activity prior to cardiac arrest, and whether death was witnessed) is collected from death certificates, Danish registries, autopsy reports, and medical records throughout the study period

### Completion date
31/12/2014

## Eligibility

### Key inclusion criteria
All deaths in Denmark within specified age groups are included in the study:
1. 2000-2006: All deaths in persons aged 1-35 years
2. 2007-2014: All deaths in persons aged 1-49 years
3. 2010: All deaths in all ages

### Participant type(s)
All

### Healthy volunteers allowed
No

### Age group
All

### Sex
All

### Key exclusion criteria
Not falling within the defined age brackets for the study.

### Date of first enrolment
01/01/2000

### Date of final enrolment
31/12/2014

# Locations

**Countries of recruitment**
Denmark

**Study participating centre**
**University Hospital of Copenhagen**
The Heart Centre
Department of Cardiology
Rigshospitalet
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# Sponsor information

**Organisation**
University Hospital of Copenhagen

**ROR**
https://ror.org/05bpbnx46

# Funder(s)

**Funder type**
Charity

**Funder Name**
The John and Birthe Meyer Foundation

**Funder Name**
The Novo Nordisk Foundation

# 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 | 01/04/2011 | | Yes | No |
| Results article | results | 01/07/2013 | | Yes | No |
| Results article | results | 01/04/2014 | | Yes | No |
| Results article | results | 01/04/2014 | | Yes | No |
| Results article | results | 01/04/2014 | | Yes | No |
| Results article | results | 01/10/2014 | | Yes | No |
| Results article | results | 14/04/2015 | | Yes | No |
| Results article | results | 01/05/2015 | | Yes | No |
| Results article | results | 01/07/2015 | | Yes | No |
| Results article | results | 01/09/2015 | | Yes | No |
| Results article | results | 01/12/2016 | | Yes | No |