ISRCTN17749344 https://doi.org/10.1186/ISRCTN17749344

Genetic causes of cardiac arrest in patients with first heart attack

Submission date	Recruitment status	[_] Prospectively registered
03/11/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2017	Circulatory System	

Plain English summary of protocol

Background and study aims
Sudden cardiac death (SCD) caused by ventricular fibrillation (VF) during a heart attack (cardiac arrest) is a leading cause of natural death worldwide. VF is a heart rhythm problem where the heart beats so rapidly and erratically, causing the chambers of the heart to quiver uselessly rather than pump blood around the body. Studies have shown that there is a genetic (inherited) component, indicating that sudden death of a family member is a risk factor for SCD and VF. Even though new insights and technology have become available, the nature of this remains poorly understood. Understanding the underlying genetic causes of SCD and VF would be a valuable means of being any to predict and prevent development of VF and develop new treatments. This study aims to evaluate the genetic components associated with VF in order to understand the underlying mechanisms.

Who can participate?
Adults having their first ST-elevations MI (STEMI – a type of heart attack) with and without VF within the first 12 hours.

What does the study involve?
Participants are recruited at the point of their STEMI. At this time, information about the participants and their medical history is collected by the researchers using questionnaires. If any information is missing, then the researchers have permission to contact the participants after they are discharged from hospital. While they are in hospital, a blood sample is collected to use for genetic analysis. After they are discharged, participants are followed up for five years to look for death of any cause by reviewing Danish nationwide registries and medical records.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. University Hospital of Copenhagen (Denmark)
2. Odense University Hospital (Denmark)
3. Aarhus University Hospital, Skejby (Denmark)
4. Aalborg University Hospital (Denmark)

When is the study starting and how long is it expected to run for?
July 2010 to July 2023

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
Dr Jacob Tfelt-Hansen

Contact details
The Heart Centre
Department of Cardiology
University Hospital of Copenhagen
Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H-3-2010-133

Study information

Scientific Title
GEnetic causes of Ventricular Arrhythmias in patients with first STEMI (GEVAMI) study

Acronym
GEVAMI

Study objectives

1. Genetic factors play a significant role in ventricular fibrillation (VF) caused by first ST-elevation myocardial infarction (STEMI)
2. VF during ischemia has a multifactorial and complex nature with a familial aggregation, implicating a genetic cause.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Committee on Health Research Ethics, 25/05/2011, protocol number: H-3-2010-133

Study design
Nationwide prospective case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ventricular fibrillation

Interventions
Participants are recruited at the point of first STEMI. Baseline demographics and previous medical history are collected by researchers by using standardized questionnaires while the participant is in hospital. If data was missing in the questionnaires, the researchers have permission to contact the patient after the discharge. In addition, medical records are collected and the comprehensive Danish nationwide registries are used to describe comorbidities and for follow up. Blood sample is collected during hospitalisation, often at the same time as participants undergo routine blood testing. This is used for future genetic analysis.

Participants are followed up continuously for 5 years by reviewing Danish registries to assess for all-cause mortality.

Intervention Type
Other

Primary outcome measure

Common and rare genetic variants associated with ventricular fibrillation (VF) during first ST-elevation myocardial infarction (STEMI), analysed by genome-wide association studies and next generation sequencing

Secondary outcome measures
All-cause mortality is measured using the Danish registries continuously for 5 years

Overall study start date
03/07/2010

Completion date
03/07/2023

Eligibility

Key inclusion criteria
Cases
1. First STEMI patients who experienced VF within the first 12 hours of symptoms of STEMI before PPCI
2. Age between 18 and 80 years
3. Caucasians
4. Cardiac symptoms lasting ≤12 hours
5. Acute ST-segment elevation revealed by ECG

Controls:
1. First STEMI patients who did not have VF during the first 12 hours of symptoms of STEMI before PPCI
2. Age between 18 and 80 years
3. Caucasians
4. Cardiac symptoms lasting ≤12 hours
5. Acute ST-segment elevation revealed by ECG

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500 cases and 1500 controls

Key exclusion criteria

1. Cases and controls who developed VF during PPCI will be excluded because VF during PPCI is believed to be reperfusion induced; however, case patients with VF before PPCI who continued to have VF during PPCI can participate
2. Other exclusions included VF after PPCI
3. Congenital heart defects
4. Known structural heart disease
5. Use of class I and III antiarrhythmic drugs
6. Recent cancer
7. Major surgery or trauma within 4 weeks
8. Presentation with potassium concentration of <3 or >5 mmol/L
9. Because we also planned to identify genetic markers associated with VF, and because >90% of the Danish populations are white Danes, we excluded non-white Danes to reduce the risk of population stratification for future genetic analysis

Date of first enrolment
03/07/2011

Date of final enrolment
03/07/2020

Locations

Countries of recruitment
Denmark

Study participating centre
University Hospital of Copenhagen
The Heart Centre
Department of Cardiology
Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

Study participating centre
Odense University Hospital
Department of Cardiology
Søndre Blvd. 29
Odense
Denmark
5000

Study participating centre

Aarhus University Hospital, Skejby
Department of Cardiology
Palle Juul-Jensens Blvd. 99
Aarhus
Denmark
8200

Study participating centre
Aalborg University Hospital
Department of Cardiology
Hobrovej 18-22
Aalborg
Denmark
9100

Sponsor information

Organisation
University Hospital of Copenhagen

Sponsor details
The Heart Centre
Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, around one year after your overall trial end date.

Intention to publish date
03/07/2024

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	05/01/2015		Yes	No