

# Primary ventricular fibrillation and sudden death during a first myocardial infarction: Genetic basis

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>18/11/2016   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>29/12/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>17/12/2020       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Sudden cardiac arrest (SCA) is a serious medical condition in which the heart suddenly stops beating and is a major cause of death in people across all age groups. There is some evidence suggesting that an inherited predisposition for primary ventricular fibrillation (a heart rhythm abnormality), which occurs in the early stages of a heart attack, could be related to risk of death from SCA. The aim of this study is to look at the relationship between inherited factors (genetic variants) in patients having their first heart attack to with and without ventricular fibrillation.

### Who can participate?

Adults aged 75 years or over who have had a heart attack with or without ventricular fibrillation.

### What does the study involve?

After agreeing to take part, participants have a blood sample taken which is then frozen. In addition, information about their medical history and personal characteristics is collected using questionnaires. One year later, participants have their medical records reviewed in order to find out how many are still living. The blood samples provided at the start of the study are also tested to find out if there is a link between genes and their risk of developing ventricular fibrillation in the 24 hours following their heart attack.

### 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?

Fondazione IRCCS Policlinico San Matteo (Italy)

### When is the study starting and how long is it expected to run for?

April 2009 to December 2020

### Who is funding the study?

Università degli Studi di Pavia (Italy)

Who is the main contact?  
Professor Gaetano Maria De Ferrari  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
20130005044

## Study information

**Scientific Title**  
Assessment of genetic predisposition to development of primary ventricular fibrillation in patients with acute myocardial infarction

**Acronym**  
PREDESTINATION

**Study objectives**  
The aim of this study is to identify genetic variants that could be involved in the development of ventricular fibrillation in the 24 hours following the first myocardial infarction.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

The Bioethics Committee (IRB) of the Fondazione IRCCS Policlinico San Matteo, 06/04/2009, ref: P-20090008508

Amendment approved: 17/11/2013

## **Study design**

Multi-centre case-control observational study

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Myocardial infarction

## **Interventions**

Following provision of informed consent, all participants have a blood sample taken which is immediately frozen for the future primary outcome analysis. Peripheral blood samples are drawn into n°3 BD Vacutainer blood tubes (containing 3,2% sodium citrate) of 3,5 ml each and immediately stored at -80°C. After a reasonable amount of patients is enrolled (around n°50), Genomic DNA is extracted using a magnetic particle-based methodology (Maxwell 16 Blood DNA purification kit, Promega), according to the manufacturer's recommendations. All DNAs' concentrations is determined by spectrophotometry (Nano-Drop, Celbio) and is then normalized at an appropriate concentration for downstream analyses.

Information about medical history and demographic data is also collected. Survival status 1 year after the index event will also be collected through medical record review.

## **Intervention Type**

Other

## **Primary outcome(s)**

Genetic loci associated with ventricular fibrillation risk during myocardial infarction are assessed through analysis of 1,536 SNPs (single nucleotide polymorphisms) using the GoldenGate method (Illumina) with a custom-made chip and the Genome Wide Association Study (GWAS) technique at 1 year.

## **Key secondary outcome(s)**

1. Relationship between the occurrence of ventricular fibrillation and
  - 1.1. familiarity for sudden death
  - 1.2. Smoking habit
  - 1.3. Hypokalemia
  - 1.4. Hyperkalemia
  - 1.5. Prolonged corrected QT intervalis assessed using information collected using case reports collected at baseline
2. Survival status is assessed through medical record review at one year

## **Completion date**

31/12/2020

# Eligibility

## Key inclusion criteria

Cases:

1. Age between 18 and 75 years, inclusive
2. At least one episode of cardiac arrest due to ventricular fibrillation within 24 h of onset of symptoms of heart attack documented in the index electrocardiogram

Controls:

1. Age between 18 and 75 years, inclusive
2. Episode of myocardial infarction within 24 h of onset of symptoms

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

Case Patients Exclusion criteria:

1. Age younger than 18 or older than 75 years
2. History of previous myocardial infarction
3. Pre-existing significant cardiac disease and / or associated with Ejection Fraction less than or equal to 30%
4. Presence of arrhythmogenic diseases that affect the occurrence of major ventricular arrhythmias (TV, FV) independently by the ischemic event (arrhythmogenic right end/or left ventricular cardiomyopathies, long- and short-QT syndrome; Brugada syndrome and Catecholaminergic polymorphic ventricular tachycardia)

Control Patients Exclusion criteria:

1. Age younger than 18 or older than 75 years
2. History of previous myocardial infarction
3. Pre-existing significant cardiac disease and / or associated with Ejection Fraction less than or equal to 30%
4. Presence of arrhythmogenic diseases that affect the occurrence of major ventricular arrhythmias (TV, FV) independently by the ischemic event (arrhythmogenic right end/or left ventricular cardiomyopathies, long- and short-QT syndrome; Brugada syndrome and Catecholaminergic polymorphic ventricular tachycardia)

## Date of first enrolment

01/09/2009

**Date of final enrolment**

01/07/2019

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

Fondazione IRCCS Policlinico San Matteo

Piazzale Golgi 19

Pavia

Italy

27100

## Sponsor information

**Organisation**

Università degli Studi di Pavia

**ROR**

<https://ror.org/00s6t1f81>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Università degli Studi di Pavia

## 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

