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

Submission date 18/11/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/12/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/12/2020	**Condition category** Circulatory System	[_] Individual participant data [_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Comittee (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

Secondary study design
Case-control study

Study setting(s)
Hospital

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
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 measure
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.

Secondary outcome measures
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 interval
is assessed using information collected using case reports collected at baseline
2. Survival status is assessed through medical record review at one year

Overall study start date
06/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4000

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 cardiomiopathies, long- and short-QT syndrome; Brugada syndrome and Cathecolaminergic polymorphic ventricular tachicardia)

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 cardiomiopathies, long- and short-QT syndrome; Brugada syndrome and Cathecolaminergic polymorphic ventricular tachicardia)

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
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Sponsor information

Organisation
Università degli Studi di Pavia

Sponsor details
Area Ricerca - Servizio Ricerca e Terza Missione
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Sponsor type

University/education

ROR
https://ror.org/00s6t1f81

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Pavia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal after all samples will be analized for primary endpoint.

Intention to publish date
31/12/2021

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