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ARREST registry: Amsterdam resuscitation studies

Submission date
08/12/2016

Recruitment status
Recruiting

Registration date
08/12/2016

Overall study status
Ongoing

Last Edited
14/08/2019

Condition category
Circulatory System

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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. It is commonly caused by cardiac arrhythmia (heart rhythm disorder) and is the most common cause of death in the developed world. These heart rhythm disorders are caused by complex interactions between various factors such as inherited factors, lifestyle factors and environmental factors. A SCA is lethal within minutes if left unteated, in particular, rapid defibrillation (a shock to the chest to get the heart pumping again) and resuscitation are crucial to increase chances of survival. This, along with prevention strategies are the best ways for prventing death from SCA. The difficulty with these strategies lies in the fact that SCA generally occurs unexpectedly and out-of-hospital. Because of this, it is usually very difficult to obtain clear information about all the factors that have caused the SCA in that particular person. The ARREST registry is designed to resolve these difficulties by improving understanding of the causes of SCA in the community and by evaluating the most effective treatments of SCA. To achieve this aim, the ARREST registry includes all out-of-hospital SCA cases in a particular region of the Netherlands, collecting information of the factors that may underlie SCA occurrence, along with detailed data on the ways in which resuscitation was performed. The aim of this study is to evaluate the ARREST registry and its use in understanding the causes of SCA and the best treatments.

Who can participate?
All individuals in the ARREST region (North-Holland province of the Netherlands) who suffer out-of-hospital SCA.

What does the study involve?
Information about sudden cardiac arrest (SCA) patients is collected from the emergency medical services, hospital, general practitioner, public pharmacy, and public registries; DNA is collected from residual material taken for the sake of patient care (e.g., blood samples). Patients are enrolled in this study when they suffer SCA. They cannot provide informed consent prior to enrolment, because occurrence of SCA is presently unpredictable. Informed consent can also not be obtained during SCA, because SCA is a medical emergency, in which the patients are unconscious. Therefore, informed consent can only be obtained afterwards. Survivors of SCA are therefore contacted after they have recovered sufficiently to have regained their ability to make

an informed decision to provide written consent to participate in this study. If they decide not to participate, the patient is withdrawn from the study and DNA samples will be destroyed.

What are the possible benefits and risks of participating?
A possible benefit is that this study improves the ability to prevent SCA (SCA victims are at increased risk of suffering SCA again), and to develop more effective treatments for out-of-hospital SCA. There are no risks involved with participating.

Where is the study run from
Department of Cardiology, Heart Center, Academic Medical Center (Netherlands)

When is study starting and how long is it expected to run for?
June 2005 to December 2031

Who is funding the study?
1. European Commission: Horizon 2020 (Belgium)
2. Netherlands CardioVascular Research Initiative (Netherlands)
3. Netherlands Organization for Scientific Research (Netherlands)
4. Dutch Medicines Evaluation Board (Netherlands)
5. Dutch Heart Foundation (Netherlands)
6. Zoll Medical (Netherlands)
7. Cardiac Science (USA)
8. ZonMW (Netherlands)
9. Laerdal Foundation (Netherlands)

Who is the main contact?
1. Dr Hanno Tan (scientific)
2. Dr Marieke Blom (scientific)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
ARREST registry: AmsteRdam REsuscitation STudies

Acronym
ARREST

Study objectives
1. Sudden cardiac arrest may be prevented by understanding the interactions between the underlying causative factors
2. Sudden cardiac arrest may be better treated by designing more effective out-of-hospital treatment strategies

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Ethics Committee Academic Medical Center Amsterdam, 28/03/2007, ref: 07.17.0430
2. Biobank Ethics Committee Academic Medical Center Amsterdam, 27/03/2016, ref: 2015_125

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

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
Out-of-hospital cardiac arrest

Interventions
No interventions will be conducted specifically for the sake of this study. Data of the sudden cardiac arrest (SCA) patients will be collected from the emergency medical services, hospital, general practitioner, public pharmacy, and public registries; DNA will be collected from residual material taken for the sake of patient care (e.g., blood samples).

Patients are enrolled in this study when they suffer SCA. They cannot provide informed consent prior to enrolment, because occurrence of SCA is presently unpredictable. Informed consent can also not be obtained during SCA, because SCA is a medical emergency, in which the patients are unconscious. Therefore, informed consent can only be obtained afterwards. Survivors of SCA will therefore be contacted after they have recovered sufficiently to have regained their ability to make an informed decision to provide written consent to participate in this study. If they decide not to participate, the patient will be withdrawn from the study and DNA samples will be destroyed.

Intervention Type
Other

Primary outcome measure
1. Causes of SCA are measured by studying genetic material, medication history from the patient's pharmacist, medical data retrieved from the patient's general practitioner and/or treating hospital and (social) environmental data retrieved from the national statistics agency.
2. Survival after out-of-hospital SCA, measured at hospital discharge using hospital records, and 30-day survival using basic civic registry

Secondary outcome measures
Quality of life after surviving SCA is measured using score on Cerebral Performance Category at hospital discharge.

Overall study start date
01/01/2005

Completion date
01/01/2031

Eligibility

Key inclusion criteria
All patients who suffer out-of-hospital cardiac arrest in the ARREST study region

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
15,000

Key exclusion criteria
There are no exclusion criteria

Date of first enrolment
01/06/2005

Date of final enrolment
01/01/2030

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Department of Cardiology
Meibergdreef 9
1105 AZ Amsterdam
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Sponsor information

Organisation
Academic Medical Center (AMC)

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Sponsor type
Research organisation

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
European Commission: Horizon 2020

Funder Name
Netherlands CardioVascular Research Initiative: The Dutch Heart Foundation, Dutch Federation of University Medical Centres, the Netherlands Organisation for Health Research and Development, and the Royal Netherlands Academy of Sciences (PREDICT project)

Funder Name
Netherlands Organization for Scientific Research (NWO)

Funder Name
Dutch Medicines Evaluation Board (MEB/CBG)

Funder Name
BBMRI-NL

Funder Name
Dutch Heart Foundation

Funder Name
Physio-Control Inc

Funder Name
Zoll Medical

Funder Name
Cardiac Science

Funder Name
ZonMW

Funder Name
Laerdal Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, yearly throughout the study.

Intention to publish date
08/12/2017

Individual participant data (IPD) sharing plan
Not expected to be available, because of privacy considerations: risk of exposing patient identifying information. Data are held at Academic Medical Center, Amsterdam.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/08/2014	14/08/2019	Yes	No