

# Epigenetic Biomarkers in Sudden Cardiac Arrest

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To study whether epigenetic profiles of study participants who suffered an out-of-hospital cardiac arrest (OHCA) that were collected immediately after OHCA (in ARREST biobank) are similar their epigenetic profiles collected at least 9 months after...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON49594

### Source

ToetsingOnline

### Brief title

Epigenetic Biomarkers in Sudden Cardiac Arrest

### Condition

- Cardiac arrhythmias

### Synonym

out-of-hospital cardiac arrest, sudden cardiac arrest

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** EU Horizon 2020 subsidie

## Intervention

**Keyword:** epigenetics, sudden cardiac arrest

## Outcome measures

### Primary outcome

Epigenetic profile / markers.

### Secondary outcome

Not applicable.

## Study description

### Background summary

The causes of out-of-hospital cardiac arrest (OHCA) are highly complex and not fully resolved. To elucidate these causes, we set up the ongoing ARREST study, a community-based study in which consecutive victims of all-cause OHCA in one contiguous region (N-Holland province) are registered and their medical data and environmental factors are collected. We also collect a biobank of DNA samples extracted from residual blood samples taken after OHCA for patient care in order to study genetic factors that contribute to OHCA. In the present study, we aim to test the hypothesis that epigenetic factors also contribute to OHCA risk. This hypothesis stems from indications that OHCA risk is partly determined by environmental factors such as diet, smoking or socio-economic/psychosocial stress; these factors impact on the human genome by altering its transcriptional regulation. To test this hypothesis, we plan to analyse the epigenetic profiles of the DNA samples in the biobank. However, a potential difficulty is the fact that these samples were obtained after OHCA had already occurred, while it is unknown whether OHCA per se alters the epigenetic profile. If so, the epigenetic profile found in these samples is confounded by the effects of OHCA, rendering it unclear to which extent they also caused OHCA. To rule out this possibility, we plan to conduct the present study, in which we compare the epigenetic profiles from 15 study participants of samples in the biobank with samples that will be collected at least 9 months after OHCA. We assume that the OHCA-induced changes in epigenetic profiles (if at all present), will have abated, and the epigenetic profiles will have returned to their pre-OHCA values by that time.

### Study objective

To study whether epigenetic profiles of study participants who suffered an out-of-hospital cardiac arrest (OHCA) that were collected immediately after OHCA (in ARREST biobank) are similar their epigenetic profiles collected at least 9 months after OHCA. This is done to determine whether the epigenetic profile is a cause, rather than the result of the OHCA.

## **Study design**

Cohort study of 15 adult study participants who suffered an out-of-hospital cardiac arrest (OHCA). The epigenetic profiles of their DNA samples previously collected and stored in the ARREST biobank will be compared to newly collected DNA samples taken at least 9 months after OHCA.

## **Study burden and risks**

Participation in the trial means that the study participant has to answer questions about their smoking habits, medication use and socio-economic status. Study participants will have their blood drawn once. Their visit for this study will be combined with their regular visit to the cardiology outpatient clinic as much as possible. There are no direct benefits for the study participant. Minimal risks (associated with one-time blood draw) are associated with this intervention. However, the benefits for the population could be large.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

The patients need to have had an out-of-hospital cardiac arrest, and have to be treated in the Academic Medical Centre (Amsterdam). Additionally, we include only men and they need to have given consent to participation in the ARREST study and to being contact again in light of the ARREST study.

### Exclusion criteria

Patients are excluded when they are smokers, or when they have rigorously changed their lifestyle since their sudden cardiac arrest.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 23-12-2020

Enrollment: 15

Type:

Actual

## Ethics review

Approved WMO

Date:

27-05-2019

Application type:

First submission

Review commission:

METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

**ID**

CCMO

NL68702.018.19