# Life After Cardiac Arrest

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1. To determine the level of cognitive, emotional and cardiorespiratory impairment, daily functioning, participation in society, quality of life and partner strain up to one year after the survival of a cardiac arrest.2. To determine prognostic...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON35340

**Source**
ToetsingOnline

**Brief title**
LACA

### Condition

- Cardiac arrhythmias
- Encephalopathies
- Cognitive and attention disorders and disturbances

**Synonym**
cardiac arrest, sudden cardiac death

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Hoensbroek Revalidatiecentrum (HRC)
**Source(s) of monetary or material Support:** Zon MW,Nuts/ OHRA

## Intervention

**Keyword:** cardiac arrest, cognitive impairment, participation in society, quality of life

## Outcome measures

### Primary outcome

Participation in society and quality of life.

### Secondary outcome

Cognitive, emotional and cardiorespiratory impairment, daily functioning and

caregiver strain.

# Study description

### Background summary

Although more and more is known about the pathophysiology and acute care of cardiac arrests, information about long-term consequences and prognostic factors for future functioning are lacking. A substantial number of cardiac arrest survivors suffer from hypoxic brain injury what can result in cognitive problems. However, these cognitive impairments are frequently not recognised. This can lead to limitations in daily functioning and participation, what is expected to lead to a decreased experienced quality of life in the patient, and a high strain for the caregiver. As the number of cardiac arrest survivors is expected to increase, due to the faster access to external defibrillators, more knowledge on the quality of survival is essential. Also the effect of a follow-up programme by a specialised nurse, what is currently not existing, should be examined.

### Study objective

1. To determine the level of cognitive, emotional and cardiorespiratory impairment, daily functioning, participation in society, quality of life and partner strain up to one year after the survival of a cardiac arrest.
2. To determine prognostic factors for cognitive impairment, daily functioning, participation in society, and quality of life one year after a cardiac arrest.
3. To perform an effect and economic evaluation of a routine early intervention service.

### Study design

Prospective cohort study with a nested randomised controlled clinical trial.

### Intervention

The intervention group receives a routine early intervention service consisting of several contacts with a specialised nurse. The intervention is directed at early detection of (cognitive) problems, information supply and provision of support to the patients and their caregiver. If indicated, the patient can be referred to specialised care. The control group receives care as usual.

### Study burden and risks

This study will have a low burden and has minimal risks associated with participation. The burden for all participants consists of three measurements during one year. Participants who also take part in the randomised controlled trial also have to fill out a cost diary or questionnaire. Half of the participants in the randomised controlled trial will be allocated to the early intervention service, and will receive extra attention and care, what is expected to be perceived positively.

## Contacts

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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

Survivor of a cardiac arrest
Survival after cardiac arrest > 2 weeks
Admitted in or to one of the participating hospitals
Living within 50 km of one of the participating hospitals
18 years or older
Sufficient knowledge of Dutch language

### Exclusion criteria

General: Severe non-cardiac co-morbidity with a life expectancy lower than 3 months.
For participation in randomised controlled trial: Participant was living in an institutional care facility prior to the cardiac arrest.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Health services research

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2007 |
| Enrollment: | 240 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 14-03-2007 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 13-06-2007 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 15-06-2007 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 29-03-2010 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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 | NL15753.068.06 |