

Life After Cardiac Arrest

Published: 14-03-2007

Last updated: 14-05-2024

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...

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

Public

Hoensbroek Revalidatiecentrum (HRC)

Zandbergsberg 111
6432 CC Hoensbroek
NL

Scientific

Hoensbroek Revalidatiecentrum (HRC)

Zandbergsberg 111
6432 CC Hoensbroek
NL

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

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

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

Ethics review

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