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Activity and Life After Survival of a Cardiac Arrest

Submission date 04/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/06/2007	**Overall study status** Completed	
Last Edited 26/05/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
date 08-02-2007/ version 2

Study information

Scientific Title
Activity and Life After Survival of a Cardiac Arrest

Acronym
ALASCA

Study objectives
1.1. The level of cognitive, emotional and cardiorespiratory impairment, daily functioning, participation in society and quality of life are expected to be lower than in the general population. Daily functioning and participation in society are lower than before the cardiac arrest. Caregiver strain is expected to be higher than in the general population
1.2. Cognitive functioning is significantly related to participation in society and quality of life. Participation is significantly related to quality of life. Caregiver strain is higher when the levels of functioning of the cardiac arrest survivor are lower
2. Expected prognostic factors for cognitive impairment, daily functioning, participation in society and quality of life one year after a cardiac arrest are: age, educational level, early Cardiopulmonary resuscitation (CPR), initial cardiac rhythm, duration of the hypoxic period (interval collapse-to-return of spontaneous circulation), Glasgow Coma Score at admission, application of mild therapeutic hypothermia, duration post-traumatic amnesia, Implantable Cardioverter Defibrillator (ICD) placement, cognitive functioning (measured with O-log) at two weeks, cardiorespiratory functioning, presence of a caregiver
3.1. The routine early intervention service after survival of a cardiac arrest is more effective than usual care with regard to the level of participation in society and quality of life
3.2. The routine early intervention service is cost-effective compared to usual care
3.3. The routine early intervention service has an acceptable cost-utility (cost per Quality Adjusted Life Year [QALY])

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Commitee of Maastricht University/Maastricht Academic Hospital, 14/03/2007

Study design
Prospective cohort study with a nested randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Survivors of a cardiac arrest, hypoxic brain injury

Interventions
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 patient and their caregiver. If indicated, the patient can be referred to specialised care. The intervention will take place during the first three months after the cardiac arrest. Participants will have three to six consultations with the specialised nurse.

The control group receives care as usual.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Participation in society
2. Quality of life

All outcome measures will be admistered two weeks, three months and one year after the cardiac arrest.

Key secondary outcome(s))
1. Cognitive, emotional and cardiorespiratory impairment
2. Daily functioning
3. Caregiver strain

All outcome measures will be admistered two weeks, three months and one year after the cardiac arrest.

Completion date
01/04/2011

Eligibility

Key inclusion criteria
All survivors of a cardiac arrest (survival greater than two weeks) admitted at or to one of the participating hospitals between April 2007 and April 2011

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Severe non-cardiac co-morbidity with a life expectancy lower than three months
2. Participant was living in an institutional care facility prior to the cardiac arrest

Date of first enrolment
01/04/2007

Date of final enrolment

01/04/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Rehabilitation Foundation Limburg
Hoensbroek
Netherlands
6430 AB

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
The Nuts-Ohra Foundation (Stichting Nuts Ohra [SNO]) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	process evaluation results	23/01/2014		Yes	No
Results article	results	15/08/2015		Yes	No
Protocol article	protocol	27/08/2007		Yes	No