Activity and Life After Survival of a Cardiac Arrest

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Véronique Moulaert

Contact details

Research Department Rehabilitation Foundation Limburg P.O. Box 88 Hoensbroek Netherlands 6430 AB

v.moulaert@srl.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

- 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.

Secondary outcome measures

- 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.

Overall study start date

01/04/2007

Completion date

01/04/2011

Eligibility

Kev 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

Age group

Not Specified

Sex

Not Specified

Target number of participants

240

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)

Sponsor details

P.O. Box 93245 Den Haag Netherlands 2509 AE

Sponsor type

Research organisation

Website

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?

Protocol article	protocol	27/08/2007	Yes	No
Results article	process evaluation results	23/01/2014	Yes	No
Results article	results	15/08/2015	Yes	No