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Arrest 8: maximizing cardiopulmonary resuscitation (CPR) during the use of the automatic external defibrillator

Submission date 07/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2006	**Overall study status** Completed	
Last Edited 22/06/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Cardio-pulmonary resuscitation (CPR) is a first aid technique that can be used if someones heart has stopped (cardiac arrest). Chest compressions and rescue breathing by lay rescuers and professionals are essential components in saving a victim's life, besides other measures such as defibrillation with an Automated External Defibrillator (AED), a machine that delivers an electric shock to the heart when someone is having a cardiac arrest. Interruptions of chest compressions should be avoided as much as possible. We found in earlier studies that AEDs cause interruptions because they prompt the rescuer what to do with an electronic voice. Among the voice instructions are several moments of stopping chest compressions for heart rhythm analysis and checking the pulse. Analysis of cases revealed that such prompts may not be needed for good CPR. We designed a different set of voice prompts for AEDs that could reduce the hands-off time during CPR and possibly improve outcome.

Who can participate?
All patients in out-of-hospital cardiac arrest in the study area, to whom an AED is applied.

What does the study involve?
The cases will be randomly allocated into two groups. For half of the cases the AED will speak the voice prompts as used before, and in the other half of the cases the voice prompts will be of the new kind with less hands-off time. A rescuer employing an AED just follows the voice prompts and that does not change. Only the order of voice prompts is different and some commands are removed.

What are the possible benefits and risks of participating?
The benefit could be more success in bringing back the patients pulse and regaining consciousness. Ultimately it should result in more patients admitted alive to the hospital and after that more patients being discharged alive. There are no particular risks to the new procedure compared to the old procedure.

Where is the study run from?
Academic Medical Center (AMC) (Netherlands)

When is the study starting and how long is it expected to run for?
June 2006 to January 2014

Who is funding the study?
Medtronic BV (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR652

Study information

Scientific Title
Arrest 8: maximizing cardiopulmonary resuscitation (CPR) during the use of the automatic external defibrillator

Study objectives

1. There is a significant increase in the time spent on chest compressions and rescue breathing using new designed voice-prompts.
2. There is, similar to animal studies, a positive trade-off in immediate survival from these changes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
AMC Medical Ethics Committee (Medisch Ethische Commissie AMC), 15/12/2005, MEC 05/195 #05.17.1602

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Out-of-hospital cardiac arrest (OHCA)

Interventions
Altering the voice prompts of the AED in such a way that more CPR can be given during resuscitation. Setting of AED regular voice prompts versus new voice prompts cannot be identified before patient is connected to the AED. After that randomization is unblinded as the next voice prompts are different.

Intervention Type
Device

Primary outcome measure
Admission alive in the hospital in intensive care unit (ICU) or critical care unit (CCU) or at intervention procedure, after restoration of spontaneous circulation (ROSC).

Secondary outcome measures
1. The increase of total time spent on chest compressions and rescue breathing, expressed as a percentage of total connection time of the AED before return of spontaneous circulation (ROSC)

2. Amount of chest compressions given during the AED connection time before ROSC
3. Moment of the return of organized rhythm (ROOR), in this case, ROOR during AED use
4. Rate of recurrence of VF
5. Discharged alive from the hospital
6. Overall performance categories/cerebral performance categories (OPC/CPC) score on discharge from the hospital

Overall study start date
01/06/2006

Completion date
31/01/2014

Eligibility

Key inclusion criteria
All patients in out-of-hospital cardiac arrest (OHCA) in the study area, to whom a study automatic external defibrillator (AED) is applied

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
392

Key exclusion criteria
1. Resuscitations because of trauma
2. Persons below the age of 8
3. Ambulance already present when circulatory arrest occurs

Date of first enrolment
01/06/2006

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Center (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (Netherlands)

Sponsor details
PO Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/?pid=2581

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Medtronic BV (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?
Results article	results	01/02/2010		Yes	No
Results article	results	01/09/2016		Yes	No