Arrest 8: Maximizing CPR during the use of the Automatic External Defibrillator.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25217

Source
NTR

Brief title
N/A

Health condition

OHCA with application of an AED by first responders

Sponsors and support

Primary sponsor: Academisch Medical Centrum
Meibergdreef 9
1105 AZ Amsterdam
Source(s) of monetary or material Support: Medtronic ERS
Redmond, WA
USA

Intervention

Outcome measures

Primary outcome

Admission alive in the hospital in ICU or CCU or at intervention procedure, after restoration of

spontaneous circulation (ROSC).

Secondary outcome

1. The increase of total time spent on chest compressions and rescue breathing, expressed as % of total connection time of the AED before ROSC;
2. Amount of chest compressions given during the AED connection time before ROSC;
3. Moment of ROOR, cq ROOR during AED use;
4. Rate of recurrence of VF;
5. Discharge alive from the hospital;
6. OPC/CPC score at discharge from the hospital.

Study description

Background summary

Background: The use of the AED, paradoxically, proved to be a cause of withholding BLS during substantial periods.
Intervention: This information has resulted in voice prompt changes, based on best available evidence.
Design: The study aims to improve the use of the AED in patients with out-of-hospital cardiac arrest and the maximal application of chest compressions and ventilations during application of the AED. The study is per-patient randomized and controlled with AEDs with “regular” voiceprompt settings. All patients in out-of-hospital cardiac arrest, to whom a study-AED is applied, are included in the study. Exclusion criteria are resuscitations because of trauma; persons below the age of 8 years (AED not allowed); ambulance already present when circulatory arrest occurs.
Endpoint: The primary endpoint of the study is admission alive in the hospital after being stabilized in the field and/or in the Emergency Room. Unblinding is unavoidable at the start of use of the AED, as the “regular” and “experimental” voice prompt design are clearly different. Outcome assessment for the primary outcome therefore is objective but not blinded.

Study objective

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

Intervention

Altering the voiceprompts of the AED in such a way that more CPR can be given during resuscitation. Setting of AED (regular voice prompts vs. new voiceprompts cannot be

identified before patient is connected to the AED. After that randomization is unblinded as the next voiceprompts are different.

Contacts

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Eligibility criteria

Inclusion criteria

All patients in OHCA in the study area, to whom a study-AED is applied, are included in the study.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	392
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-04-2006
Application type:	First submission

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
NTR-new	NL596
NTR-old	NTR652

Register	ID
Other	: N/A
ISRCTN	ISRCTN72257677

Study results

Summary results
N/A