

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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25217

Bron

NTR

Verkorte titel

N/A

Aandoening

OHCA with application of an AED by first responders

Ondersteuning

Primaire sponsor: Academisch Medical Centrum

Meibergdreef 9

1105 AZ Amsterdam

Overige ondersteuning: Medtronic ERS

Redmond, WA

USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Admission alive in the hospital in ICU or CCU or at intervention procedure, after restoration of spontaneous circulation (ROSC).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2006
Aantal proefpersonen:	392
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-04-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ISRCTN

ID

NL596

NTR652

: N/A

ISRCTN72257677

Resultaten

Samenvatting resultaten

N/A