ON-SCENE Initiation of Extracorporeal CardioPulmonary Resuscitation During Refractory Out-of-Hospital Cardiac Arrest

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In this study, we aim to improve survival to hospital discharge and costs/QALY in young patients with OHCA by decreasing the time in cardiac arrest by initiating ECPR on scene.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON52845

Source
ToetsingOnline

Brief title
ON-SCENE ECPR study

Condition

- Heart failures
- Encephalopathies

Synonym
Cardiac Arrest, ECPR

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac Arrest, ExtraCorporeal Cardiopulonary Resuscitation, PreHospital

Outcome measures

Primary outcome

Hospital survival and costs/QALY (EQ-D5), favourable neurological outcome (CPC 1-2) at 6 and 12 months after cardiac arrest.

Secondary outcome

To study the health care costs per OCHA patient (iPCQ, iMCQ), costs per Quality Adjusted Life Year (QALY), Quality of life 6 and 12 months after OHCA and total costs per life gained in the intervention group and in the control group

Study description

Background summary

Approximately half of all cardiac arrest patients achieve return of spontaneous circulation (ROSC) within 10 minutes. However, If ROSC is not achieved within 20 minutes, favourable neurological outcome is rare. Nowadays, patients without ROSC at scene, die at scene, or are transported (while in cardiac arrest) to the hospital. In the hospital, advanced life support is continued, or, patients receive Extracorporeal CardioPulmonary Resuscitation (ECPR). ECPR is a strategy in which a miniaturized heart-lung machine (similar to that used in open-heart surgery) is attached to the patient. Nowadays, the greatest drawback transporting OHCA patients with refractory arrest to the hospital is the long time needed to arrive in the hospital. In the Netherlands, Helicopter Emergency Medical Services (HEMS) deliver highly specialized medical care to trauma and non-trauma patients, covering the entire country. We hypothesize that implantation of on-scene ECPR by the HEMS teams in patients with out-of-hospital cardiac arrest, results in the rapid return of circulation and, thus, improved survival and less neurological impairment, which is associated with lower health care costs.

Study objective

In this study, we aim to improve survival to hospital discharge and costs/QALY

in young patients with OHCA by decreasing the time in cardiac arrest by initiating ECPR on scene.

Study design

Multicenter, stepped-wedge trial, comparing deployment of HEMS not equipped with ECPR with HEMS equipped with ECPR in patients with a witnessed out-of-hospital cardiac arrest between the age of 18 and 50 years old.

Intervention

Initiation of ECPR prehospital, delivered by the HEMS teams. In the control group, HEMS teams will provide Advanced Life Support following the national guidelines.

Study burden and risks

The potential benefits for patients who are included in this study is that additional medical expertise is added, in the control group and intervention group. Moreover, in the intervention group, early termination of the cardiac arrest state by mechanically restoring bloodflow will most probably result in an improved survival. On the other hand, potential risks are the inability of cannulation in ongoing cardiac arrest, and vascular complications. These risks are minimalized by a very extensive training program as shown by a pilot performed at Erasmus MC. Moreover, multiple studies have shown that ECPR cannulation by intensivist in the hospital or pre-hospital performed by emergency physicians is safe and feasible. Despite the training, multiple studies, as well as data from the ErasmusMC, still show a 10% inability of cannulation rate and a 10% vascular complications rate. Despite of the complication rate, this study has probably major survival benefits for the patients to participate, which outweighs the potential risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age between 18 and 50 years
- Witnessed arrest (last seen well <5 min), OR signs of life (gasping, movement)
- Initial rhyme is VT/VF OR Suspected of having a pulmonary embolism
- Refractory cardiac arrest lasting longer than 20 minutes and shorter than 45 min

Exclusion criteria

- CO2 et<1.2 kPa (10 mmHg) during CPR
- No clear echographic visualisation of either the femoral artery or the femoral vein.
- Expected time from collapse to arrival at an ECPR center with a direct available ECPR team is less than 30 min.
- Patients from a dispatch region which is not ready to deploy HEMS on a routine basis for OHCA patients with the age between 18 and 50 years.

The following patients will be withdrawed after initial inclusion as soon as the following information becomes available:
- Known malignancy
- Known intracranial haemorrhage/ischemia <6 weeks
- Care dependent for daily activities before arrest
- Patients with a *do not resuscitate* order, which was not known at time of the arrest.
- Refusal of defferred consent by the next of kin or by the patient himself to

use the data.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2021
Enrollment:	390
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-11-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-08-2022
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-11-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT04620070
CCMO	NL73073.078.20