Early initiation of extracorporeal life support in refractory out-of-hospital cardiac arrest

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

Summary

ID

NL-OMON55387

Source
ToetsingOnline

Brief title
INCEPTION trial

Condition

- Heart failures

Synonym
Cardiac arrest; ventricular fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: CPR, ECPR, OHCA, VF

Outcome measures

Primary outcome

30-days survival rate with favourable neurological status (Cerebral Performance Category (CPC) score of 1 or 2)

Secondary outcome

neurological outcome at 3 months, 6 months and 12 months, survival benefit (Quality Adjusted Life Years, QALY), costs per QALY

Study description

Background summary

Chances of survival in case of out-of-hospital cardiac arrest (OHCA) are small. After 15 minutes of resuscitation survival declines sharply. In case of ventricular fibrillation/tachycardia (VF/VT) there is often a treatable underlying cause. During resuscitation however, diagnostic and therapeutic options are severely limited. With the use of extracorporeal cardiopulmonary resuscitation (ECPR) can circulation be restored, gaining precious time to diagnose and treat the underlying problem. Current data on this subject is retrospective and non-randomized, but a possible benefit is suggested.

Study objective

We aim to investigate ECPR in a prospective manner since earlier retrospective studies have suggested that application of ECPR during refractory arrest increases the chance of survival and decreases neurological damage. In a randomized, multi-center trial it can also be examined whether routine use of ECPR in refractory cardiac arrest can be economically justified by performing a cost-effectiveness analysis.

Study design

Randomized controlled multi-center trial

Intervention

Patients will be randomized to either receive ECPR or continued conventional CPR (CCPR).

Study burden and risks

The chances of survival with good neurological outcome of a refractory OHCA due to VF/VT are small. Performing ECPR on these patients may substantially increase their chances on survival with a good neurological outcome as suggested by retrospective research. ECPR does have high risks associated with the treatment itself, e.g. bleeding, infection, ischemia of a leg, thrombosis, cannula displacement and circuit failure. However, the potential increase in chances of survival with good neurologic outcome is large enough to accept these risks.
Thirty days, three months, six months and twelve months after the OHCA the patients or their families will be asked to fill in questionnaires to assess their neurological status and several patient related outcome measures. Apart from these questionares there is no additional burden associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- ventricular fibrilation
- <=70 years
- >=18 years
- > 15 minutes no circulation
- whitnessed out-of-hospital cardiac arrest
- Bystander BLS

Exclusion criteria

- ROSC within 15 minutes of conventional CPR with sustained hemodynamic recovery
- Terminal heart failure (NYHA III or IV)
- Severe pulmonary disease (COPD GIII of GIV)
- Disseminated oncological disease
- Obvious or suspected pregnancy
- Bilateral femoral bypass surgery
- Known contraindications for ECPR
- Known pre-arrest Cerebral Performance Category 3 or 4
- Known limitations in therapy or a Do Not Resuscitate-order
- Multi-trauma (Injury Severity Score >15)
- > 60 minutes before start cannulation procedure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2017
Enrollment:	134
Type:	Actual

Ethics review

Approved WMO Date:	01-03-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-04-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-05-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	03-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT03101787
CCMO	NL58067.068.16