

Intravenous Access during Resuscitation

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To compare the effects of central versus peripheral drug administration on the rate of return of organised electrical activity and/or spontaneous circulation during CPR.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON37486

Source

ToetsingOnline

Brief title

IVAR Trial

Condition

- Heart failures

Synonym

circulatory arrest

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiopulmonary resuscitation, circulatory arrest, intravenous access

Outcome measures

Primary outcome

Combined primary endpoint: rate of appearance of organised electrical activity or return of spontaneous circulation.

Secondary outcome

- time to primary endpoints
- Complications following external jugular cannulation: arterial puncture, bleeding.
- Does central external jugular cannulation interfere with chest compressions?
- Time needed for obtaining jugular access.
- 1- and 7- day survival rate.

Study description

Background summary

Vascular access for drug administration during cardiopulmonary resuscitation (CPR) is routinely obtained in the extremities. During chest compression facilitated circulation, however, circulating blood is preferential directed to the heart and brain at the expense of abdominal organs and peripheral circulation. Peripheral administration could therefore limit the efficacy of resuscitation drugs that must reach the heart, their primary site of action, as effectively as possible.

Previous animal studies reported faster and higher central peak drug concentrations during CPR after central versus peripheral administration. This finding was supported in a small human study. However, this evidence in favour of central drug administration appears to have been neglected. In addition, it is undetermined whether pharmacokinetic differences between central and peripheral access routes are clinically relevant.

We hypothesize that, during CPR, central administration of resuscitation drugs, compared to standard treatment via a peripheral access, is associated with enhancement of signs of cardiac effects of these drugs, in particular return of organised electrical activity and/or of spontaneous circulation.

Study objective

To compare the effects of central versus peripheral drug administration on the rate of return of organised electrical activity and/or spontaneous circulation during CPR.

Study design

Randomized clinical trial

Intervention

Central venous access

Study burden and risks

All patients are treated according to the guidelines of the European Resuscitation Council, which are endorsed by the local VUMC CPR-committee. Central access will be obtained by cannulation of the external or internal jugular vein by an experienced physician. To avoid interference with initial management, central venous access will be obtained after initiation of chest compressions, first attempt at defibrillation (if applicable), securing the airway and obtaining a peripheral access.

All resuscitated patients require vascular access and almost all successfully resuscitated patients require central venous access. Obtaining central access during CPR may be associated with a slightly higher complication rate, such as arterial puncture and pneumothorax. Possible benefits for study subjects are a higher success rate of CPR.

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

Hospitalized patients and patients presenting at the emergency department, older than 18 years, requiring cardiopulmonary resuscitation

Exclusion criteria

- age <18 years
- circulatory arrest following major bleeding or trauma
- central venous access in-situ at time of commencement of CPR

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO	
Date:	28-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL40187.029.12