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Monitoring of tissue oxygen levels during out-of-hospital cardio-pulmonary resuscitation

Submission date
25/07/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
14/08/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiac arrest is a major cause of death in developed nations and the death rate after cardiac arrest has not improved significantly in recent years. Although almost half of patients being resuscitated with cardiopulmonary resuscitation (CPR) regain spontaneous circulation (ROSC), the majority of these patients do not achieve a good neurologic outcome, as brain is most at risk to even short periods of hypoxia (lack of oxygen) during cardiac arrest. The aim of this study is to better understand and help guide resuscitation efforts during CPR, mostly predicting success or ineffectiveness (futility) of ongoing CPR.

Who can participate?
The study will enrol all adult patients (of both genders) in cardiac arrest where CPR will be started and treated by our local Prehospital medical unit (EMS) in Maribor, Slovenia.

What does the study involve?
We will observe the dynamics of oxygen supply to the brain following cardiac arrest during standard CPR. The study does not involve or compare any treatment, it is an observation with new monitoring technology, namely near-infrared spectroscopy (NIRS).

What are the possible benefits and risks of participating?
All patients enrolled in the study will receive standard treatment as per international guidelines. Due to the observational nature of the study, patients themselves will not gain any direct benefit, but knowledge gained by our study will enhance our understanding in the field of cardiac arrest and CPR.

Where is the study run from?
The study is run from and will be conducted in a single centre in Maribor, Slovenia.

When is the study starting and how long is it expected to run for?
The study started in June 2012 and is expected to run until July 2014 or until we are able to enrol 60 patients. Patients will be recruited as cardiac arrest events happen.

Who is funding the study?
The study has no additional funding, it will be conducted as part of regular work at the Center for Emergency Medicine, Maribor, Slovenia

Who is the main contact?
Gregor Prosen, MD
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
18041979

Study information

Scientific Title
Monitoring of cerebral tissue oxygenation during out-of-hospital cardio-pulmonary resuscitation

Study objectives
We hypothesise that continous cerebral tissue oxygenation (StO2) with Near-Infrared spectroscopy (NIRS) during cardio-pulmonary resuscitation (CPR) in pre-hospital setting can help us predict success of CPR and even final neurologic outcome of these patients. Our main hypotheses are, that continuously low or undetectable levels of cerebral StO2 predict unsuccessful CPR and that rapid restoration of normal or near-normal StO2 levels predicts good outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by Slovenian National Ethics Committee, on 22nd may 2012, No. 123/05 /12

Study design

Two-year observational longitudinal study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cardiac arrest, cardiopulmonary resuscitation

Interventions
The study does not involve/compare any interventions. It is observational study during standard CPR treatment.

We will be observing trending of values of cerebral tissue partial oxygen pressure (ScO2) during standard cardiopulmonary resuscitation (CPR). Initial values of ScO2 of patients found in cardiac arrest in field are expected to be very low/critical or mostly even unmeasurable and we hypothesize that dynamic changes during CPR will be able to predict outcome.
ScO2 will be observed for total duration of CPR, from commencing of chest compressions until successful return of spontaneous circulation (ROSC) or pronouncement of dead/stoping CPR efforts.
Parallel to ScO2 measurements, we will be also observing end-tidal CO2 (EtCO2) during CPR and basic vitals signs achieved after ROSC.
Patients that will achieve ROSC and will be successfully transported to Hospital, will be followed up until discharge from hospital (usually weeks).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Return of spontaneous circulation (ROSC) will be assessed immediately during CPR, eg. the patient either achieves ROSC (successful CPR) or patient is pronounced dead in the field. ROSC assesment is made in standard manner, by palpating carotid pulse.

Key secondary outcome(s))
1. Neurologic outcome will be measured at the discharge from hospital by assesment with "Glasgow-Pittsburgh cerebral performance category scale" (CPC scale).
2. Discharge from hospital will measure total duration spent in ICU (intensive care unit), time patient needed mechanical support on ventilator and time until discharge from hospital

Completion date
01/06/2014

Eligibility

Key inclusion criteria

All adult (male and female >18 years) in cardiac arrest, where treating physicians has decided to commence CPR

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
53

Key exclusion criteria
1. Traumatic cardiac arrest
2. Intoxication
3. Drowning
4. Age <18 years

Date of first enrolment
01/06/2012

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Slovenia

Study participating centre
Gregorciceva 48
Maribor
Slovenia
2000

Sponsor information

Organisation
Center for Emergency Medicine Maribor (Slovenia)

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Center for Emergency Medicine Maribor (Slovenia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018	14/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes