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The use of erythropoietin in cardiac arrest victims: the impact on survival and neurological outcome

Submission date 03/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/07/2007	**Overall study status** Completed	
Last Edited 21/09/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CNMPEPO 001

Study information

Scientific Title

Acronym
CNMPEPO

Study objectives
Pre-hospital teams are often confronted with a problem of cardiac arrest patients. Every minute without CPR reduces survival by 10 to 15%. In our pre-hospital setting there is 50% success in returning the spontaneous circulation (Return Of Spontaneous Circulation, ROSC) after CPR. Only half of these patients survive to discharge from hospital.
That is why more thoughts should be pointed to intra- and post-reanimation care meaning preservation and protection of the brain and heart function. Only this provides the chance of survival to be wholesome. Immediately after ROSC there is a period of brain hyperemia. 15 to 30 minutes after ROSC brain perfusion decreases and because the autoregulation of the brain is lost, perfusion of the brain mainly depends upon mean arterial pressure. Brain oedema, focal haemorrhages and instability of circulation lead to further brain ischaemic lesions.

The aim of our research is to determine the impact of erythropoietin on survival and neurological outcome of cardiac arrest victims. On the basis of previous preclinical and clinical data about eryrhropoietin (EPO) therapy for acute stroke and acute myocardial infarction we expect that giving erythropoietin early in the course of cardiopulmonary resuscitation would decrease the ischaemic and reperfusion damage to the brain and heart.

Hypothesis: The group of patients in cardiac arrest who are treated with erythropoietin have better survival (discharge from hospital) and neurological outcome (Cerebral Performance Category [CPC]). We expect that giving erythropoietin early in the course of cardiopulmonary resuscitation would decrease the ischaemic and reperfusion damage to the brain and heart after a period of cardiac arrest and thus it would improve neurological outcome of these patients. Key questions are:
1. What is the survival rate of the patients who received EPO compared to those who didn't?
2. Does the new approach to the cardiac arrest victims improve their survival?
3. Is there any difference in the neurological outcome between the two groups?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Medical Ethics Committee of Republic of Slovenia, approved on 23/01/2007 (ref: KME 37/01/07)

Study design
Prospective, multi-centre (three emergency medical service centres) randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiac arrest

Interventions
The patients in the intervention group will receive a bolus of EPO (90000 IU) in first four minutes during the CPR process. Intraosseous route is an alternative. Early application of the drug is crucial to cover the period of ischaemia and reperfusion which are both connected with brain in myocardial injury and possibility of malignant heart arrhythmias. In the case of ROSC all the patinets will be cooled down by the process of induced therapeutic hypothermia receiving sterile physiological saline with the temperature of 4°C and the speed 100 ml/hour.

Both intervention and control groups (group with and without erythropoietin) will be treated according the latest guidelines for cardiopulmonary resuscitation (the International Liaison Committee on Resuscitation [ILCOR] - European Resuscitation Council).

All the data will be collected under the ILCOR recommendation in Utstein style and checked by two independent researchers. Neurological function of the patients will be assessed and categorized with Cerebral Performance Score (CPS).

The following data will also be collected:
1. Capnometry
2. Initial heart rhythm
3. Age
4. Gender
5. Withness of cardiac arrest
6. Lay bystanders CPR
7. Response time
8. Respiratory Rate (RR)
9. Echocardiography
10. Protein S 100
11. Creatinine Kinase (CK)
12. Sodium (Na)
13. Chloride (Cl)
14. Pottasium (K)
15. Calcium (Ca)
16. Magnesium (Mg)
17. Lactate
18. Brain Computed Tomography (CT)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
erythropoietin

Primary outcome measure
Neurological outcome assessed by CPC, from CPC-1 (normal neorological status) to CPC-5 (brain death). This will be measured six months after cardiopulmonary resuscitation.

Secondary outcome measures
1. ROSC in the field (%)
2. ROSC with admission to hospital
3. 24-hour survival
4. Survival (discharge from hospital)

Overall study start date
01/06/2007

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. 18 years or older
2. Non-traumatic, cardiac arrest in pre-hospital setting when started with cardiopulmonary reanimation irrespective of initial cardiac rhythm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Traumatic cardiac arrest
2. Under 18 years of age
3. Cardiopulmonary Resuscitation (CPR) without drugs (only defibrillation)
4. Pregnancy
5. Severe hypothermia (<30°C)

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Slovenia

Study participating centre
Ulica talcev 9
Maribor
Slovenia
2000

Sponsor information

Organisation
Centre for Health and Emergency Medicine (Zdravstveni dom adolfa drolca maribor) (Slovenia)

Sponsor details
Ulica talcev 9
Maribor
Slovenia
2000

Sponsor type
Hospital/treatment centre

Website
http://www.zd-mb.si/

ROR
https://ror.org/01j9yjt02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Centre for Health and Emergency Medicine (Zdravstveni dom adolfa drolca maribor) (Slovenia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/06/2009		Yes	No