

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
Registration date 20/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/09/2009	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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 erythropoietin (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

Study type(s)

Treatment

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 patients 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. Witness 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. Potassium (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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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