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Resuscitation in hostile environments

Submission date	Recruitment status	[X] Prospectively registered
03/01/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Thousands of people suffer a cardiac arrest every day, but the state of their heart presents conditions to survive. The lack of cardiac activity produces an absence of perfusion to all the organs of the body, producing a tissue damage that can be definitive and irreversible if one does not act quickly and in a coordinated way. Thus, the satisfactory survival of cardiac arrest depends on a concatenated series of critical interventions. To achieve the greatest possibility of survival for victims suffering cardiac arrest, it is necessary to replace the essential functions to maintain cerebral, pulmonary and cardiac perfusion. Perform a conventional resuscitation requires training, training and why not say, certain physical conditions to be able to tolerate for the time necessary to perform the techniques and also do it with the necessary quality. Develop a resuscitation under a hostile environment, both for victims and rescuers, such as situations such as extreme environmental temperatures, increased body weight of resuscitators, use of personal protective equipment against biological or chemical risks, resuscitation at altitude , etc., implies an increase in metabolic needs, marking a strategy of action and reaction in the intervention very different from that performed in conventional scenarios.

Who can participate?
Any person over 18 with certified knowledge (ERC or AHA) in basic resuscitation.

What does the study involve?
Physiological, metabolic and psychological impact on resuscitators when performing a basic cardiopulmonary resuscitation for 10 minutes. The proposed practical case is the same, a cardiac arrest in which the personnel present at the scene (1 rescuer) must perform the resuscitation techniques for 10 minutes until the arrival of the specialized help. The case of resuscitation is the same for the five proposed study scenarios, and basic resuscitation norms of the ERC and / or AHA will be followed. The proposed scenarios are: control group, warm environment, cold environment, weight gain and resuscitation with PPE against biological risk. In all simulation scenarios, volunteers must perform the same resuscitation techniques, under the same sequence of events and for 10 minutes. The treatment of all the participating subjects will be similar, except in the intervention (resuscitation environment), performing the same measures and interventions before and after intervention.

What are the possible benefits and risks of participating?
The benefits for the participants lie in the fact of collaborating in the study for scientific

purposes. During the realization of resuscitation in hostile environments participants (even if they are exceptional) can have some adverse effect, among which are: dizziness or faintness, loss of consciousness, hypotension / hypertension, tachycardia, anxiety crisis, hypoglycemia , alterations of thermoregulation, injuries in the putting and removal of the suit, injuries during the realization of resuscitation, pain in the puncture site, in exceptional cases inflammation and local infection, skin rash can be provoked. The team of researchers is prepared to solve the complications and adverse effects that may arise, stopping the study before the slightest doubt. In any scenario, a complete team of advanced life support will be prepared with material for handling the airway, oxygen and aspiration; venous via material, including drugs commonly used in emergencies; and manual defibrillator monitor.

Where is the study run from?
The study will be developed in the Faculty of Medicine of the University of Valladolid and in the Faculty of Nursing of the University of Castilla la Mancha (Spain).

When is the study starting and how long is it expected to run for?
The study is scheduled to begin in March 2019 and end in December 2019

Who is funding the study?
The study is funded by the research team. There are no external subsidies.

Who is the main contact?
Francisco Martín-Rodríguez, PhD
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Contact information

Type(s)
Scientific

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Protocol serial number
178013/I30

Study information

Scientific Title

Randomized controlled clinical trial on basic cardiopulmonary resuscitation and metabolic fatigue in in wilderness environments

Acronym
RinWE

Study objectives
Hostile environments can increase metabolic stress and therefore metabolic fatigue directly affecting the quality of the maneuvers performed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2019, Ethical Research Committee of the Integrated Health Area of Talavera de la Reina (General Hospital Our Lady of the Prado, Carretera de Madrid, Km. 114, 45600 Talavera de la Reina, Toledo, Spain; (925) 803600 Ext 86316; varroyo@sescam.org), ref: 4/2019.

Primary study design
Interventional

Study design
Randomized, multi-centre randomised controlled clinical trial with double-blind masking and 1: 1 allocation ratio.

Study type(s)
Other

Health condition(s) or problem(s) studied
Metabolic fatigue

Interventions
The proposed practical case is the same, a cardiac arrest in which the personnel present in the scene (1 rescuer) must perform the reanimation techniques for 10 minutes until the arrival of the specialized help. The cardiac arrest case is the same for the five proposed study scenarios, and basic reanimation standards of the ERC and / or AHA will be followed. Before beginning any of the cases, it will be explained that they must perform the techniques and procedures on the simulation dummy as correctly as possible, since the physiological and metabolic impact of the resuscitation on the participant and the quality of the maneuvers are evaluated. employed, both. During the entire reanimation process, continuous monitoring of the heart rate, respiratory rate and electrocardiographic rhythm of each volunteer will be performed to assess their constants and immediately detect possible complications. In addition, every two minutes (minutes 2-4-6-8 and 10) a serial curve of lactic acid will be made by capillary and pH extractions by means of saliva samples. The extraction will be done coinciding with the ventilation cycles during the reanimation sequence.

1. Group 1 (control). The subjects will perform a basic reanimation in a laboratory of 20 m2 with good illumination, temperature of 21 ºC, humidity of 60%, individually, with the sequence of 30 compressions and two ventilations.
2. Group 2 (intervention: warm environment). The subjects will perform a basic reanimation in a laboratory of 20 m2 with good illumination, temperature of 40 ºC, humidity of 98%, individually,

with the sequence of 30 compressions and two ventilations.
3. Group 3 (intervention: freezing environment). Subjects will perform a basic reanimation in a 20 m2 cold storage room with good illumination, temperature of 0°C, humidity of 80%, individually, with the sequence of 30 compressions and two ventilations.
4. Group 4 (intervention: overweight). The subjects will perform a basic reanimation in a laboratory of 20 m2 with good illumination, temperature of 21 °C, humidity of 60%, individually, with the sequence of 30 compressions and two ventilations. To increase the metabolic stress to each subject who performs this scenario will be placed a ballasted vest with a weight equivalent to 10% of their body weight.
5. Group 5 (intervention: incidents with biological risk). The subjects will perform a basic reanimation in a laboratory of 20 m2 with good illumination, temperature of 21 °C, humidity of 60%, individually, with the sequence of 30 compressions and two ventilations. Volunteers will wear an appropriate category 4B personal protective equipment (PPE) to work in biohazardous environments. The implementation and withdrawal protocol was based on the recommendations of the European Center for Disease Prevention & Control

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following are assessed before the participant performs the simulation:
1. Respiratory frequency, assessed using clinical observation
2. Oxygen saturation, assessed using an Masimo Rad 7
3. Heart rate, assessed using a Physio LifePAK® 15 monitor
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000
6. Lactic acid levels, assessed using an Accutrend® Plus meter
7. Blood glucose, assessed using an Accu-Chek® Aviva
8. pH, using saliva strips
9. Hemoglobin level, assessed using an Masimo Rad 7
10. Perfusion index, assessed using an Masimo Rad 7

The following are assessed at the moment the participant performs the simulation every two minutes:
1. Respiratory frequency, assessed using clinical observation
2. Heart rate, assessed using a Physio LifePAK® 15 monitor
3. Lactic acid levels, assessed using an Accutrend® Plus meter
4. pH, using saliva strips
5. Quality level of resuscitation, using the Little Anne QCPR simulator (Laerdal) with QCPR software

The following are assessed at the participant performs the simulation, after 10 minutes of rest:
1. Respiratory frequency, assessed using clinical observation
2. Oxygen saturation, assessed using an Masimo Rad 7
3. Heart rate, assessed using a Physio LifePAK® 15 monitor
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000
6. Lactic acid levels, assessed using an Accutrend® Plus meter
7. Blood glucose, assessed using an Accu-Chek® Aviva

8. pH, using saliva strips
9. Hemoglobin level, assessed using an Masimo Rad 7
10. Perfusion index, assessed using an Masimo Rad 7

Key secondary outcome(s)
The following are assessed before and after the simulation:
1. Anthropometric study, carried out with the Tanita BC541-N smart scale
2. Anxiety study, through the STAI questionnaire
3. Study of the level of physical activity, using the IPAQ short form questionnaire (this parameter is only evaluated before beginning the study)

Completion date
10/12/2019

Eligibility

Key inclusion criteria
1. Between 18 and 65 years of age
2. Basic knowledge of basic resuscitation (accredited course or equivalent to the training of AHA or ERC)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
59

Key exclusion criteria
1. Basal heart rate greater than 120 or less than 35 beats per minute.
2. Electrocardiogram with alterations: arrhythmias or changes in the ST segment.
3. Systolic or diastolic blood pressure greater than 160 or 95 mmHg respectively.
4. Systolic blood pressure less than 80 mmHg.
5. Abnormal spirometry (best of three attempts).
6. Oxygen saturation less than 92%.
7. Capillary glycemia below 65 mg / dl.
8. Body mass index greater than 40 Kg / m2.
9. Severe visual or hearing impairment
10. Functional impotence

11. Capillary hemoglobin less than 8 gr.
12. Temperature greater than 38º C.
13. Major surgery 30 days before.
14. Cutaneous diseases in acute phase.
15. Epilepsy.
16. Anticoagulation
17. Infections in progress
18. Systemic immunological diseases.

Date of first enrolment
01/03/2019

Date of final enrolment
06/06/2019

Locations

Countries of recruitment
Spain

Study participating centre
Medicine Faculty, Valladolid University
Advanced Clinical Simulation Center
Avda. Ramón y Cajal, 7
Valladolid
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47005

Study participating centre
Nursing Faculty, Castilla la Mancha University
Avda. Real Fábrica de Seda, s/n
Talavera de la Reina
Spain
45600

Sponsor information

Organisation
Universidad de Valladolid

Organisation

Universidad de Castilla la Mancha

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Francisco Martín-Rodríguez (fmartin@saludcastillayleon.es), as soon as the field phase of the study ends and the data is tabulated, up to 2 years after the end of the study. Researchers with similar studies may have access and under a properly motivated request. The data will be anonymized and only the data used in this test will be provided, at no time will be submitted names or identifying data of the participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2020	17/03/2022	Yes	No
Results article		14/06/2020	13/02/2024	Yes	No
Results article		25/11/2022	13/02/2024	Yes	No