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Compression Only CardioPulmonary Resuscitation in telephone assisted bystanders (COCPR II)

Submission date
20/03/2012

Recruitment status
No longer recruiting

Registration date
28/03/2012

Overall study status
Completed

Last Edited
13/01/2015

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims:
High quality chest compressions are vital for neurologically intact survival after cardiac arrest. Therefore bystanders are encouraged to act decisively in presence of a cardiac arrest victim. For this case, protocol based, telephone instructions for chest compressions are given by emergency dispatchers responding to emergency calls. Unfortunately quality of chest compression remains suboptimal which is understandable because bystanders are usually untrained. The aim of this study is to improve quality of chest compression by adapting telephone instructions.

Who can participate?
Your participation is voluntary. You need to be older than 18 years, give an informed consent and your blood pressure should be less than 150 mm Hg before the study starts.

What does the study involve?
We will compare a slightly adapted verbal instruction to the standard protocol based instruction set for telephone resuscitation.
If you take part two questionnaires are requested. The first one targets demographic datas such as age, smoking habits etc. The second questionnaire evaluates your physical fitness.
Afterwards, you are requested to perform a skill test evaluating fine motor skills. For this test you need to put pegs into holes with your non-dominant hand. Before the study starts your blood pressure and your heart frequency is measured.

The main study is a simulated, 10 minute, cardiopulmonary resuscitation on a manikin with human like properties. The study scenario stipulates that you are confronted with a cardiac arrest victim at home. Via telephone, a professional emergency dispatcher, will give you verbal instructions how to resuscitate the victim. The resuscitation is performed as a chest compressions only resuscitation. During the resuscitation we will ask you for your subjective perceived exertion. After you have finished the simulated resuscitation scenario we will measure your heart rate and your blood pressure again. Also, you are requested to redo the skill test.

What are the possible benefits and risks of participating?
We expect no risk for your health caused by this study. Your personal benefit will be a renewal of your basic life support skills.

Where is this study run from?
This study is organised by the Department of Emergency Medicine of the Medical University of Vienna. The study venue is a large shopping hall. Verbal instructions are given by a professional emergency dispatcher who will be situated in an emergency dispatch centre.

When is study starting and how long is it expected to run for?
This study will be performed on June, 27th 2012. Your participation will take only 15 minutes.

Who is funding the study?
The study is being funded by RORACO which will provide the Laerdal resusci anne manikin.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.1

Study information

Scientific Title
Is repeating the target depth instruction improving overall compression depth in an Advanced Medical Priority Dispatch System (AMPDS) guided, telephone compression only cardiopulmonary resuscitation? A randomized factorial simulation study

Acronym
COCPR II

Study objectives
Please note that, as of 11/05/2012, the scientific title of this trial has been changed from 'Is repeating the target depth instruction every minute improving overall compression depth in an Advanced Medical Priority Dispatch System (AMPDS) guided, telephone compression only cardiopulmonary resuscitation? A randomized parallel group simulation study' to 'Is repeating the target depth instruction improving overall compression depth in an Advanced Medical Priority Dispatch System (AMPDS) guided, telephone compression only cardiopulmonary resuscitation? A randomized factorial simulation study'

As os 11/05/2012, the study design of this trial has been changed from 'Double-blinded randomized parallel group simulation study' to 'Double-blinded randomized factorial simulation study

Repeating the telephone instruction push down firmly 5 cm improves overall compression depth.

Follow up of study registered under http://www.controlled-trials.com/ISRCTN51784217

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Medical University of Vienna, 02 February 2012

Study design
Double-blinded randomized factorial simulation study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cardiopulmonary resuscitation

Interventions

Current interventions as of 11/05/2012:

The scenario is planned as an out of hospital, telephone assisted, bystander CPR. Substantial information about circumstances (at home, compression only, telephone assisted bystander CPR) is given prior to participant. Outcome is blinded to the participants. After informed consent, participants are guided to a simulation room where the manikin is prepared. Only minimal study staff will have access to the scenario room to avoid distractions. Study staffs assignment is documentation of parameters and not to be involved into bystander CPR.

Participants will be staffed with a telephone to call the Emergency Dispatch Center (EDC). In the EDC, a professional emergency dispatcher will be providing verbal prompts via telephone to the bystander. The EMD is randomised to give different instructions. Verbal prompts, given by the EMD, are following the AMPDS protocol V12.0.

According to the factorial design we intend to investigate changes in the AMPDS protocol as follows:

Group 1: Standard instruction: "push down firmly 5 cm"

Group 2: Push down the chest 5 cm every time after initial directions

Group 3: like Group 2, but the instruction will be repeated every 20 seconds

Group 4: like Group 1, but the instruction push down firmly 5cm will be repeated every 20 seconds

The EMD has to open one opaque envelope per call to be randomised in either control or intervention. Therefore study staff are also blinded to allocation of the bystander.

Another predefined precondition is that all bystanders are denying rescue breaths. Every participant is performing closed-chest compression for 10 minutes on a slightly modified Resusci Anne® Manikin (Laerdal, Norway). Data will be collected using the Laerdal® PC Skill-Reporting System - a software used with the adult size Laerdal® Resusci® Anne SkillReporterTM manikin to collect the subjects' CPR performance.

Previous interventions:

The scenario is planned as an out of hospital, telephone assisted, bystander CPR. Substantial information about circumstances (at home, compression only, telephone assisted bystander CPR) is given prior to participant. Outcome is blinded to the participants. After informed consent, participants are guided to a simulation room where the manikin is prepared. Only minimal study staff will have access to the scenario room to avoid distractions. Study staffs assignment is documentation of parameters and not to be involved into bystander CPR.

Participants will be staffed with a telephone to call the Emergency Dispatch Center (EDC). In the EDC, a professional emergency dispatcher will be providing verbal prompts via telephone to the bystander. The EMD is randomised to give two different instructions. Verbal prompts, given by the EMD, are following the AMPDS protocol V12.0.

For the control group the standard instruction "press down firmly 5 cms is given at the beginning of the simulated CPR scenario.

For the interventional group "press down fimrly 5 cms is repeated every minute.

The EMD has to open one opaque envelope per call to be randomised in either control or intervention. Therefore study staff are also blinded to allocation of the bystander.

Another predefined precondition is that all bystanders are denying rescue breaths. Every participant is performing closed-chest compression for 10 minutes on a slightly modified Resusci Anne® Manikin (Laerdal, Norway). Data will be collected using the Laerdal® PC Skill-Reporting System - a software used with the adult size Laerdal® Resusci® Anne SkillReporterTM manikin to collect the subjects' CPR performance.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Chest compression depth, measured continously via the pc skillmeter software of the resusci anne skillmeter

Secondary outcome measures
1. Quality of ECC defined as number of percent of adequately achieved compression depth, continously assesed via skillmeter pc
2. Time to measurable decay in chest compression depth, continously assesed via skillmeter pc
3. Frequency of chest compression, continously assesed via skillmeter pc
4. Correct recoiling of the manikins chest, continously assesed via skillmeter pc
5. Heart rate/systolic blood pressure ratio reflecting physical strain, measured before and immediately after chest compression
6. BORG rate of perceived exertion measured at 2nd, 4th, 6th and 10th minute of chest compressions
7. Serum lactate changes
8. Systolic and diastolic blood pressure
9. Nine Hole Peg Test, measured before and immediately after chest compression

Overall study start date
27/06/2012

Completion date
27/06/2012

Eligibility

Key inclusion criteria
1. Voluntary participants
2. Informed Consent
3. Aged greater than 18 years
4. Blood pressure less than 150 mm Hg (systolic) before starting CPR simulation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Health care professionals
2. Basic Life Support course performed within the last 6 months
3. Pregnancy
4. Blood pressure over 150 mm Hg (systolic) before starting CPR simulation

Date of first enrolment
27/06/2012

Date of final enrolment
27/06/2012

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna (Austria)

Sponsor details

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Sponsor type
Other

Website
http://www.meduniwien.ac.at/notfall

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Industry

Funder Name
Roraco GmbH (Austria)

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	01/01/2014		Yes	No