

Compression Only CardioPulmonary Resuscitation in telephone assisted bystanders (CO CPR II)

Submission date 20/03/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/01/2015	Condition category Signs and Symptoms	<input type="checkbox"/> 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 data 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

Contact name

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Additional identifiers

Protocol serial number

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

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 of 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

Primary study design

Interventional

Study design

Double-blinded randomized factorial simulation study

Study type(s)

Treatment

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 SkillReporter™ 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 firmly 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 SkillReporter™ manikin to collect the subjects' CPR performance.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Chest compression depth, measured continuously via the pc skillmeter software of the resuscitation skillmeter

Key secondary outcome(s)

1. Quality of ECC defined as number of percent of adequately achieved compression depth, continuously assessed via skillmeter pc
2. Time to measurable decay in chest compression depth, continuously assessed via skillmeter pc
3. Frequency of chest compression, continuously assessed via skillmeter pc
4. Correct recoiling of the manikins chest, continuously assessed 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

Industry

Funder Name

Roraco GmbH (Austria)

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	01/01/2014		Yes	No