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Safety of mechanical chest compression devices in cardiac arrest: a randomised virtopsy study with the Lucas®

Submission date
10/06/2009

Recruitment status
No longer recruiting

Registration date
11/09/2009

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardio-pulmonary resuscitation (CPR) is a first aid technique that can be used if someones heart has stopped (cardiac arrest). Chest compression during CPR is hard work and many rescuers fail to achieve the required compression depth and compression rate for longer than 1-2 minutes. Also, compressions are interrupted both for good or bad reasons, possibly with a negative impact on outcome. It is not surprising that mechanical chest compression devices have been developed which could give chest compressions without interruption and without fatigue. There were great expectations that these devices could improve survival from cardiac arrest. Unfortunately, at the time of design of this study, no studies had showed that expected benefit, rather the opposite. Since our current study started, several studies have been published that also failed to show a clear benefit of mechanical chest compression compared to manual compressions.
One possible explanation could be that the potential benefit was counteracted by possibly too forceful compressions or by possible incorrect positioning of the device, causing damage to internal organs. Such damage was not demonstrated convincingly, only in some anecdotal cases. The purpose of our study is to specifically look for damage to bone structures and internal organs by means of postmortem CT scans, autopsy, or evaluation of the clinical course of the patient after successful resuscitation. All analyses are done by observers that are blind, i.e. not aware of the method of chest compression that was used in a particular patient.
There are several different ways to administer chest compressions and to achieve the desired propelling of blood. One of the ways is a device that rhythmically compresses the chest by rhythmically pushing the sternum (breastbone) inward with the recommended depth and rate. This device, Lucas, is subject of this study and is compared to manual chest compression by in-hospital rescuers.

Who can participate?
Patients aged 18 years or over, either sex, are included in the study when in cardiac arrest and requiring full CPR, which is ongoing when the resuscitation team arrives with the study device.

What does the study involve?
When the need for CPR arises in a patient, chest compressions are performed with either the Lucas device or with conventional manual chest compressions. The method used is chosen at random. If the patient does not survive, the family is approached for permission to perform a postmortem CT scan (which does not open the body but only involves an X-ray study of the intact body) or an autopsy. As the patient is unconscious from the outset of cardiac arrest, the patient is not aware of the use of either devices.

What are the possible benefits and risks of participating?
The benefit could be that more patients survive and no excess damage is done. The risk could be that the excess damage is demonstrated. As these devices are commercially available and applied widely, understanding the possible risks of its use is of great importance.

Where is the study run from?
Academic Medical Centre (AMC) (Netherlands).

When is the study starting and how long is it expected to run for?
The study ran from June 2009 to May 2014.

Who is funding the study?
Jolife AB (Sweden) and AMC Medical Research BV (Netherlands).

Who is the main contact?
Dr Rudolph Koster

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Safety of the Lucas® device in in-hospital cardiac arrest: a randomised virtopsy study to investigate the possible damage from chest compression administered by manual force compared with the Lucas® assessed blind by (post-mortem) computed tomography (CT) scanning

Acronym
Arrest 16L

Study objectives
Use of the Lucas® device during cardio-pulmonary resuscitation, compared with manual chest compression, is not associated with a significant increased probability of severe damage: immediately life-endangering or severely debilitating damage to parenchymal organs (liver, spleen, lungs), gastro-intestinal rupture, tension pneumothorax, myocardial rupture or aortic rupture, spinal, vertebral damage or flail chest.

On 28/05/2014 the anticipated end date was changed from 01/06/2011 to 26/05/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Board of the Academic Medical Center, Amsterdam, 08/11/2007, ref: 07-249

Study design
Single-centre randomised controlled part-blinded non-inferiority clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Circulatory arrest

Interventions
Investigational treatment: chest compressions with Lucas® device
Control treatment: manual chest compressions with audio-visual feedback from displacement sternum transducer

The possible damage will be assessed by blinded investigators from the post-mortem CT scan, the autopsy if available or the clinical course of (initial) survivors, if no clinically indicated CT scan is available. The seriousness of the complications observed will be distinguished in three levels of severity: life-threatening, consequential or insignificant. The damage will also be classified as related to cause of arrest or CPR related or uncertain.

Patients are followed-up until discharge or death in-hospital.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
CPR-related severe damage, defined as severe, life-threatening damage to a visceral organ in the chest or abdomen, but also including large vessels and vertebrae. Damage will be classified as primary endpoint by the data and safety committee, based on the available information, including (post-mortem) CT scans, autopsy, if performed, and clinical information in (initial) survivors.

Assessment will be done after in-hospital death or at hospital discharge.

Secondary outcome measures
Damage to bony structures of the chest wall (sternum and ribs). Assessment will be done after in-hospital death or at hospital discharge.

Overall study start date
12/06/2009

Completion date
26/05/2014

Eligibility

Key inclusion criteria
Patients (aged 18 years or older, either sex) are included in the study when in circulatory arrest, requiring full cardio-pulmonary resuscitation, which is ongoing when the resuscitation team arrives with the study device.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Non-inferiority design: 2 x 112 patients needed

Key exclusion criteria
1. Patients less than 18 years of age
2. Trauma is the cause of circulatory arrest

Date of first enrolment
12/06/2009

Date of final enrolment
26/05/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
c/o R.W. Koster
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1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/?pid=2581

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Jolife AB (Sweden) - restricted grant

Funder Name
AMC Medical Research BV (Netherlands)

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	21/10/2017	21/01/2019	Yes	No