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

Submission date 10/06/2009	Recruitment status No longer recruiting	[] Pros [] Prot
Registration date 11/09/2009	Overall study status Completed	[_] Stati [X] Resu
Last Edited 21/01/2019	Condition category Circulatory System	[] Indiv

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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 applies force to a band over the chest, causing a more general compression of the whole chest, rather than only pushing the sternum (breastbone) inward. This device, Autopulse, 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 Autopulse 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? Zoll Medical Corporation (USA) and AMC Medical Research BV (Netherlands).

Who is the main contact? Dr Rudolph Koster

Contact information

Type(s) Scientific

Contact name Dr Rudolph Koster

Contact details Academic Medical Centre (AMC) Department of Cardiology Meibergdreef 9 Amsterdam Netherlands 1105 AZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Safety of use of the AutoPulse®: a mechanical chest compression 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 AutoPulse® assessed blind by (post-mortem) computed tomography (CT) scanning

Acronym

Arrest 16A

Study objectives

Use of the AutoPulse® 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 AutoPulse® 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 will be 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 over, 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 under 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 Department of Cardiology Meibergdreef 9 Amsterdam Netherlands 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 Zoll Medical Corporation (USA) - 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