# A comparison of conventional adult out-of-hospital cardiopulmonary resuscitation against a concept with mechanical chest compressions and simultaneous defibrillation - LINC study

Published: 08-07-2008
Last updated: 11-05-2024

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33629

**Source**
ToetsingOnline

**Brief title**
LINC (LUCAS IN Cardiac Arrest) study

### Condition

- Cardiac arrhythmias

**Synonym**
circulatory arrest, sudden cardiac arrest

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Jolife AB
**Source(s) of monetary or material Support:** Jolife AB

## Intervention

**Keyword:** Cardiopulmonary resuscitation (CPR), Mechanical chest compression device, Pre-hospital, Sudden cardiac arrest

## Outcome measures

### Primary outcome

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8.1 PRIMARY ENDPOINT

• Four hour survival from successful restoration of spontaneous circulation.

This will generally mean survival to reach Intensive Care Unit (ICU) or Cardiac

Care Unit (CCU).

### Secondary outcome

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8.2 SECONDARY END POINTS

• Restoration of spontaneous circulation (ROSC) defined as spontaneous palpable

pulse.

• Arrival to the emergency room with spontaneous palpable pulse

• Survival to discharge from Intensive Care Unit (ICU) without severe

neurological impairment (Cerebral Performance Category (CPC) 1 or 2).

• Survival to hospital discharge without severe neurological impairment (CPC 1

or 2).

• Survival 1 and 6 months after cardiac arrest without severe neurological

impairment (CPC 1 or 2).

# Study description

### Background summary

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4 BACKGROUND INFORMATION
Although the number of individuals resuscitated from cardiac arrest has increased greatly as the years have passed since the first CPR standards were produced in 1974 [1], the success rate has not increased to any measurable extent. Only about 6% of victims of out of hospital cardiac arrest survive to discharge despite resuscitation attempts [2]. This includes those who have received bystander cardiopulmonary resuscitation (CPR) which can improve survival by a factor of 2.5 [3]. In Sweden, 1 month survival data from out-of-hospital cardiac arrest victims have been collected since 1990 and the figures have varied between 4-7 %. [4].One problem that militates against greater success is the difficulty to perform effective and uninterrupted compressions over time. Although the artificial maintenance of blood flow (by chest compressions) is essential for survival if a shock cannot be given very quickly, the theoretical 25% of normal cardiac output that might be obtained by compressions are unlikely to be achieved during the great majority of resuscitations. Computer print-outs from automated defibrillators show that compressions are given on average only during 36% of the available resuscitation time even when performed by experienced rescuers [5].Trained first responders who compress at a rate of 120/min when providing CPR still end up with only 38 compressions per minute over the resuscitation time because of ventilatory and other interruptions [6]. Moreover, the depth of compressions, even when given by healthcare professionals, is generally appreciably less than what is recommended in guidelines [7, 8]. Whatever quality is achieved over the first minute or so rapidly deteriorates if a single rescuer is involved [9].
New methods to achieve consistent and high quality compressions are needed.

### Study objective

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5 STUDY OBJECTIVES
5.1 PRIMARY OBJECTIVE
The primary objective is to show superiority in survival of the modified method with the LUCAS Chest Compression System, compared to the conventional manual

resuscitation method in patients suffering from out of hospital sudden cardiac arrest

Primary endpoint is four hour survival from successful restoration of spontaneous circulation. This will generally mean survival to reach Intensive Care Unit (ICU) or Cardiac Care Unit (CCU).

5.2 SECONDARY OBJECTIVES
The secondary objectives are to show superiority in survival for the modified method with the LUCAS chest compression system compared to the conventional manual resuscitation method in patients suffering from out of hospital sudden cardiac arrest by measuring the following secondary endpoints:
• Restoration of spontaneous circulation (ROSC) defined as spontaneous palpable pulse
• Arrival to the emergency room with spontaneous palpable pulse
• Survival to discharge from ICU without severe neurological impairment (Cerebral Performance Category (CPC) 1 or 2).
• Survival to hospital discharge without severe neurological impairment (CPC 1 or 2).
• Survival 1 and 6 months after cardiac arrest without severe neurological impairment (CPC 1 or 2).

**Study design**

Page numbers 7-11 of the study protocol.

**Intervention**

Page numbers 8 of the study protocol

Those randomized to treatment with LUCAS CPR will immediately be treated with manual compressions with minimized interruptions until the device is unpacked and ready to use. LUCAS Chest Compression System should be attached to the patient as soon as possible. In this group the defibrillator need to be in manual mood.

Mechanical compressions will continue initially for 3 minutes without checking the heart rhythm, irrespectively if any manual compressions have been given by bystanders or not. The first shock will be delivered during compressions after 90 seconds into the first 3 minute cycle of LUCAS compressions, followed by 90 seconds of continued compressions. This first shock will be done without analyzing underlying heart rhythm. Heart rhythm will then be determined after each 3 minute cycle by interrupting mechanical compressions briefly. This should be achieved as quickly as possible, never exceeding 10 seconds. If the analyzed rhythm is shockable, a new 3 minute cycle of compressions will start including one shock delivered after 90 seconds of ongoing compressions. If the

rhythm is not shockable, a 3 minute cycle of compressions without interruption will start followed by a new rhythm analysis. Heart rhythm and circulation will be checked after each 3 minute cycle

**Study burden and risks**

Page number 13+14 of the study protocol

9 ASSESSMENT OF SAFETY
There will be no non-serious adverse event reporting in this study. Events like rib fractures, sternum fractures and skin bruises are common after cardiopulmonary resuscitation (CPR) using either method and are not needed to be reported as adverse events. However, if events including the above mentioned occur that fall under the Serious Adverse Event definition, they should be reported as serious adverse events.

9.1 INJURIES FROM CHEST COMPRESSIONS
Autopsy will performed according to a specified Case Report Form (CRF) to investigate injuries in both study groups. Number of injuries possibly affecting survival will be studied.
This study will be done in a limited number of centres (Uppsala, Gävle and Västerås, Sweden). The goal will be to get autopsy results from a total of 300 study patients.

9.2 SERIOUS ADVERSE EVENTS - SAE
SAE is defined as an event directly related to CPR as judged by investigator/co-investigator and assumed to occur after the randomization in the study, such as incidents that have resulted in:
• Death
• Serious deterioration of health in patient. This may include
- life threatening illness or injury
- permanent deterioration of body function or structure
- prolongation of hospitalization
-conditions that require medical or surgical treatment to prevent any of the above

9.3 REPORTING OF SERIOUS ADVERSE EVENTS
The reporting by the Investigator to the Sponsor shall cover all serious AE:s, including their intensity and cause. The Investigator should report all serious AE:s by fax or phone to the Sponsor within 24 h from receiving knowledge of the event. The Investigator should use a Serious Adverse Event Report form included in the CRF file.

The Investigator*s initial report of serious AE:s should as far as possible be supplemented by detailed information on diagnosis/symptoms, and any further relevant data by a follow-up report within 7 days.

Information about SAE will be forwarded to all study sites and when applicable to the MPA by the sponsor.

9.4 ADVERSE DEVICE EVENTS - ADE

ADE is defined as any untoward and unintended response of the device, leading to that the protocol was not fulfilled due to technical issues or other circumstances. It may also include injuries on LUCAS operators or another person than the patient, which can be directly related to the device. If an ADE occurs it should be reported within 24 hours to Jolife AB, by filling an ADE report in the CRF file. The ADE will be handled according to Jolife ordinary quality system.

# Contacts

**Public**
Jolife AB

Ideon
SE-223 70 Lund
Sweden
**Scientific**
Jolife AB

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SE-223 70 Lund
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Circulatory arrest

### Exclusion criteria

1. Traumatic cardiac arrest, including hanging
2. Age believed to be less than 18 years (no upper limit)
3. Known pregnancy
4. Defibrillated before LUCAS Chest Compressions System arrives at scene
5. Patients body size not fitting the LUCAS Chest Compression System

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-11-2008 |
| Enrollment: | 800 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | LUCAS chest compression system |
| Registration: | Yes - CE intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 08-07-2008 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 04-11-2008 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 06-11-2008 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 25-11-2008 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 08-12-2008 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 21-12-2009 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 16-08-2012 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL21034.100.08 |