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# Resuscitation Hollands-Midden (RHM) study

**Submission date**
16/12/2013

**Recruitment status**
No longer recruiting

**Registration date**
21/01/2014

**Overall study status**
Completed

**Last Edited**
09/08/2019

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Ambulance services must perform resuscitation in accordance to the international guidelines. There are several (resuscitation) tools available that are supposed to improve resuscitation. Quality of cardiopulmonary resuscitation (CPR) and safety for nurse paramedics led to the implementation of the Lund University Cardiac Assist System (LUCAS) and the Boussignac endotracheal tube by the Regional Ambulance Service Hollands Midden (RAVHM) in the Leiden Hollands-Midden region in The Netherlands. The LUCAS is a pneumatic chest compression device that provides chest compressions in accordance to the guidelines of the International Liaison Committee on Resuscitation (ILCOR). The Boussignac tube is an endotracheal tube that gives a continuous flow of oxygen and generates a positive airway pressure during LUCAS resuscitation. In rural areas it will usually take a long time to get an ambulance to the patient. For this reason we also organized a system in which trained police and firefighters will be sent to the scene of a resuscitation in order to start early CPR before the ambulance arrives on scene as well.
The aim of the study is to examine the preclinical applicability of the LUCAS in combination with the Boussignac tube, the rate of return of spontaneous circulation (ROSC) on arrival at the emergency room and the effects of police and firefighters as first responders.

Who can participate?
All resuscitation patients in the Leiden who need chest compressions and/or defibrillation.

What does the study involve?
This is a observational study in which we will observe the application of LUCAS and the Boussignac tube in pre-hospital resuscitation.

What are the possible benefits and risks of participating?
Resuscitation will be performed according to the latest guidelines. All patients will benefit from the continuous, almost not interrupted chest compressions and ventilation. Patients in rural areas where the system of police and firefighter first responders is operational, will benefit from an earlier start of the resuscitation. There are no risks to be expected.

Where is the study run from?
The study will run from the Regional Ambulance Service Hollands Midden, The Netherlands.

When is the study starting and how long is it expected to run for?
The study started in November 2011 and ran until December 2013.

Who is funding the study?
Regional Ambulance Service Hollands-Midden, The Netherlands.

Who is the main contact?
Mr Jan Bosch, study coordinator
jbosch@ravhm.nl

# Contact information

### Type(s)
Scientific

### Contact name
Dr J. Nooij

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# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
Prospective single-center observational study of the applicability of the Lund University Cardiac Assist System (LUCAS) in combination with the Boussignac tube and the return of spontaneous circulation (ROSC) rates

### Acronym
RHM

### Study objectives
The study should provide insight into the preclinical feasibility of the chosen tools and the ROSC rate on arrival at an emergency room. Second, the role of the automated external defibrillator (AED), bystander cardiopulmonary resuscitation (CPR), (un)witnessed (monitored) arrest and the initial arrhythmia in the ROSC rate will be described. We will investigate the contribution of first responder fire and police departments to the percentage of resuscitation patients who have achieved ROSC on arrival on scene of the ambulance and on arrival at the hospital.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)
Ethics Board Leiden University Medical Center, 21/07/2011, P11.114

### Study design
Prospective single-center observational study

### Primary study design
Observational

### Study type(s)
Screening

### Health condition(s) or problem(s) studied
Collapse, CPR, ambulance services, ROSC

### Interventions
This is a observational study in which we will observe the application of LUCAS and the Boussignac tube in pre-hospital resuscitation. We will look at: ambulance and bystander delay; ROSC after use of an Automated External Defibrillator (AED) and bystander CPR; ROSC at witnessed, monitored witnessed and unwitnessed arrest. The observation timeline starts with the call to the emergency medical dispatcher and ends at arriving at the emergency room.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Return of spontaneous circulation (ROSC) of a resucitated patient on arrival at the emergency room

### Key secondary outcome(s))
1. Application of LUCAS and the Boussignac tube
2. Ambulance and bystander delay
3. ROSC after use of an Automated External Defibrillator (AED) and bystander/police/fire department CPR
4. ROSC at witnessed, monitored witnessed and unwitnessed arrest
5. ROSC per initial rhythm (disorder)/security/complications/awareness monitoring

### Completion date
31/12/2013

## Eligibility

### Key inclusion criteria
500 consecutive resuscitation patients without age or gender discrimination

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Sex**
All

**Total final enrolment**
433

**Key exclusion criteria**
1. Do-not-attempt-resuscitation (DNAR) order
2. Medically futile

**Date of first enrolment**
23/11/2011

**Date of final enrolment**
31/12/2013

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Postbus 121**
Leiden
Netherlands
2300 AC

# Sponsor information

**Organisation**
Regional Ambulance Service Hollands Midden (Regionale Ambulance Voorziening Hollands Midden [RAVHM])

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Regional Ambulance Service Hollands Midden (Regionale Ambulance Voorziening Hollands Midden [RAVHM]) (Netherlands)

# 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 | 01/07/2019 | 09/08/2019 | Yes | No |