

Resuscitation Hollands-Midden (RHM) study

Submission date 16/12/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/01/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/08/2019	Condition category Other	☐ 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

Contact details
Postbus 121
Leiden
Netherlands
2300 AC
+31 (0) 71 5730050
jdenooij@ravhm.nl

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 resuscitated 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