

German Automatic chest compression Resuscitation Trial

Submission date 07/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/11/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Automatic chest compressions by the AUTOpulse® resuscitation system versus conventional manual chest compressions in resuscitation from pre-hospital cardiac arrest: a prospective randomised pre-clinical trial in a GERman emergency medical system

Acronym

German ART

Study objectives

Resuscitation with the Autopulse® resuscitation system effects both a better primary and a better long term outcome after pre-hospital cardiac arrest.

Please note that as of 28/11/2008 the public title and acronym fields have been updated. The initial details were as follows:

Initial public title: Automatic chest compressions by the Autopulse® resuscitation system versus conventional manual chest compressions in resuscitation from pre-hospital cardiac arrest

Initial acronym: AUTOGER

As of 19/11/2010 this record has been updated and the public title changed to the above; the previous public title was 'German Autopulse Resuscitation Trial'. At this time, the anticipated end date was also amended; the previous end date was 09/01/2010. The target number of participants was extended from 200 to 250 - 300 participants. All other changes can be found in the relevant section.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Independent Ethics Board of the University of Bonn (Germany) on the 13th September 2007 (ref: 099/06)
2. Independent Ehtics Board of th Medical Association of North Rhine (Duesseldorf, Germany) on the 1st April 2008 (ref: 2008068) (added 28/11/2008).

Study design

Prospective, single centre, pre-clinical, randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pre-hospital cardiac arrest

Interventions

The participants will be randomised into the intervention and control groups. Both groups will receive advanced cardiac life support in accordance with the 2005 European Resuscitation Council Guidelines.

Intervention group: chest compressions by the Autopulse® resuscitation system

Control group: manual chest compressions

In addition to the intervention and control groups, a subgroup "fast Autopulse®" will be identified for the analysis of primary and secondary outcome measures. A "fast Autopulse®" patient is defined as a patient who received the first Autopulse® compression less than six minutes of the arrival of the first clinical staff at the site.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Rate of admission to hospital with a spontaneous heart rhythm and a palpable pulse.

Key secondary outcome(s)

Current information as of 19/11/2010:

The following will be analysed for the three patient groups described above:

1. 24-hours survival
2. Rate of discharge from intensive care unit
3. Rate of discharge from hospital
3. Three-month survival
5. One-year survival
6. Overall and neurological performance at these four defined points of time

Initial information at time of registration:

The following will be analysed for the three patient groups described above:

1. Rate of discharge from intensive care unit
2. Rate of discharge from hospital
3. Three-month survival
4. One-year survival
5. Overall and neurological performance at these four defined points of time

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Patients of the emergency medical system with resuscitation from pre-clinical cardiac arrest of non-traumatic origin
2. Both genders
3. Aged 18 - 80 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Cardiac arrest of traumatic origin
2. Aged less than 18 or greater than 80 years (known or estimated)
3. Extreme adiposity (estimated chest circumference greater than 150 cm or estimated weight greater than 150 kg)
4. Pregnancy (known or visually noticeable)
5. Time taken from 112 call to physician's arrival at the site greater than 15 minutes

Date of first enrolment

10/01/2008

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Germany

Study participating centre

Universitätsklinikum Bonn

Bonn

Germany

53105

Sponsor information

Organisation

University of Bonn (Germany)

ROR

<https://ror.org/041nas322>

Funder(s)

Funder type

University/education

Funder Name

University of Bonn (Germany) - Department of Anaesthesiology and Intensive Care Medicine

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration