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German Automatic chest compression Resuscitation Trial

Submission date	Recruitment status	[ ] Prospectively registered
07/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/11/2010	Circulatory System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
Current infomation 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

Overall study start date
10/01/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients of the emegency 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250 - 300 (as of 19/11/2010, previously 200)

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)

Sponsor details
c/o Dr M Breil
Rheinische Friedrich-Wilhelms-Universität
Universitätsklinikum
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Sponsor type
University/education

Website
http://www.uni-bonn.de

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

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