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The key technology and standard of mechanical circulatory support

Submission date	Recruitment status	[ ] Prospectively registered
21/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/04/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/04/2015	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A cardiac arrest happens when your heart stops pumping blood around the body. Cardiopulmonary resuscitation is then performed to keep blood and oxygen circulating in the body. Cardiopulmonary resuscitation machines have replaced manual cardiopulmonary resuscitation in many hospitals. However, there is not enough evidence to support or refute the routine use of mechanical cardiopulmonary resuscitation in the treatment of cardiac arrest. The aim of this study is to evaluate the effectiveness of mechanical cardiopulmonary resuscitation in critical patients with cardiac arrest.

Who can participate?
Men or women aged over 18 with cardiac arrest.

What does the study involve?
Participants in the test group were treated with mechanical cardiopulmonary resuscitation; participants in the control group were treated with manual cardiopulmonary resuscitation.

What are the possible benefits and risks of participating?
The possible benefit of participating is a better prognosis. The possible risk of participating is rib fracture.

Where is the study run from?
1. The Second Affiliated Hospital of Harbin Medical University
2. West China Hospital of Sichuan University
3. Sichuan Provincial People's Hospital
4. Zhongnan Hospital of Wuhan University
5. The First Affiliated Hospital of Xi'an Jiaotong University
6. Zhejiang Hospital
7. The First Affiliated Hospital of China Medical University
8. The First Affiliated Hospital of Zhongshan University

When is the study starting and how long is it expected to run for?
From March to December 2013.

Who is funding the study?
National Health and Family Planning Commission of the People's Republic of China.

Who is the main contact?
Dr KaiJiang Yu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multicenter study on the standardized application of mechanical cardiopulmonary resuscitation in patients with cardiac arrest

Study objectives
To evaluate the efficacy of mechanical cardiopulmonary resuscitation in critical patients with cardiac arrest.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the Second Affiliated Hospital of Harbin Medical University, 10/05/2013

Study design
Multicenter prospective observational study

Primary study design
Observational

Secondary study design
Prospective observational study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiac arrest

Interventions
From 01/03/2013 to 15/07/2013 patients with cardiac arrest underwent manual cardiopulmonary resuscitation according to international guidelines (control group). The CPR machine was introduced in our ICU in July 2013. Doctors and nurses in our ICU were trained how to use the CPR machine from 16/07/2013 to 15/08/2013. From 16/08/2013 to 31/12/2013 we used mechanical CPR devices for the treatment of cardiac arrest (test group).

Intervention Type
Procedure/Surgery

Primary outcome measure
Survival rate for 4 hours after starting cardiopulmonary resuscitation

Secondary outcome measures
1. Survival to hospital discharge
2. Neurological status among survivors - cerebral performance category at 4, 24 , 48 and 72 hours after starting cardiopulmonary resuscitation

Overall study start date
01/03/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria

1. Men or women included in each center during the study period aged more than 18 years
2. First occurrence of cardiac arrest in the ICU, or transferred to the ICU after the first occurrence of cardiac arrest
3. Cardiac arrest must be less than 30 minutes before cardiopulmonary resuscitation in the ICU

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. No resuscitation attempts with the cardiac arrest occurred for more than 3 minutes
2. Unable to carry out chest compressions (such as serious rib injury)
3. Cardiac arrest after thoracic surgical operation
4. Low temperature, poisoning, drowning or hanging caused the cardiac arrest
5. Mentally disabled
6. Pregnant women

Date of first enrolment
01/03/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital of Harbin Medical University
China

Study participating centre
West China Hospital of Sichuan University
China

Study participating centre
Sichuan Provincial People's Hospital
China

Study participating centre
Zhongnan Hospital of Wuhan University
China

Study participating centre
The First Affiliated Hospital of Xi'an Jiaotong University
China

Study participating centre
Zhejiang Hospital
China

Study participating centre
The First Affiliated Hospital of China Medical University
China

Study participating centre
The First Affiliated Hospital of Zhongshan University
China

Sponsor information

Organisation
National Health and Family Planning Commission of the People's Republic of China

Sponsor details
Beijing city
Xicheng District
1 Xizhimenwainan Road

Bejing
China
100044

Sponsor type
Government

ROR
https://ror.org/052eegr76

Funder(s)

Funder type
Government

Funder Name
National Health and Family Planning Commission of the People's Republic of China

Alternative Name(s)
Ministry of Health of China, National Health and Family Planning Commission, Chinese Health and Family Planning Committee

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
We intend to publish our study in the future. We are analyzing the data now.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request