

The key technology and standard of mechanical circulatory support

Submission date 21/03/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/04/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 27/04/2015	Condition category Circulatory System	☐ Individual participant data ☐ 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
Dr KaiJiang Yu

ORCID ID
<https://orcid.org/0000-0003-3365-1988>

Contact details
150 Haping Street
Nangang District
Harbin
China
150081

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Survival rate for 4 hours after starting cardiopulmonary resuscitation

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request