

Effects of resuscitation with sodium bicarbonate on cardiac function in patients with early-phase septic shock

Submission date 26/05/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/11/2008	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Zhi Xun Fang

Contact details

1-1 Zhong-fu Road
Nanjing
China
210003
+86 025 58802968
fangzhixun@yahoo.com.cn

Additional identifiers

Protocol serial number

TS 9904

Study information

Scientific Title

Acronym

ESBRPSS

Study objectives

To compare the effects of normal solution, 3.5% hypertonic saline solution and 5% sodium bicarbonate on cardiac output and blood pressure, in patients with early phase septic shock, when given fluid resuscitation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Health Office of Jiangsu Provincial Government on 17/03/2000, reference number: TS 9904 and by all the hospital ethical committees namely: Ethics Committee of the Second Hospital of Nanjing on 07/04/2000, reference number: 200001; the Ethics Committee of the First People's Hospital of Huai'an City on 24/10/2000, reference number: 200002; the Ethics Committee of the People's Hospital of Gaochun County on 09/08/2000, reference number: G200001; the Ethics Committee of the First Hospital of Nanjing on 22/03/2001, reference number: 200103 and the Ethics Committee of the Jiangsu Provincial Hospital on 25/03/2001, reference number: 200108.

Primary study design

Interventional

Study design

Randomized controlled trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiac functions in patients with early-phase septic shock

Interventions

Subjects are randomly assigned to three groups:

1. The Ns group: patients are injected with 5 ml/kg of normal solution (n = 30)
2. The Hs group (n=30), patients are injected with 5 ml/kg of 3.5% sodium chloride
3. The Sb group (n = 30), patients are injected with 5 ml/kg of 5% sodium bicarbonate within 15 min at initial treatment (T0 min)

At 100 min after T0 min, all the patients are injected with 20 ml/kg of 0.9% normal saline.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sodium bicarbonate

Primary outcome(s)

Cardiac output (CO) and mean arterial pressure during 8 hours after starting fluid treatment

Key secondary outcome(s)

1. Respiratory rate, heart rate and temperature
2. Blood gas and electrolyte
3. 28-day mortality

Completion date

31/10/2005

Eligibility

Key inclusion criteria

Patients with early phase septic shock (according to the criteria of the American College of Chest Physicians/Society of Critical Care Medicine). The criteria for inclusion is fulfilment of two out of the four criteria for the systemic inflammatory response syndrome (SIRS) and a systolic blood pressure lower than 90 mmHg or a reduction of 40 mm Hg from baseline.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients with a myocardial infarction, hemorrhagic shock, trauma, pregnancy, do-not-attempt-resuscitation orders, or immediate surgery requirement are excluded.

In order to focus the study on the subject of early phase septic shock, the patients with last-phase septic shock characterized by coma, seizure, diffusing intravascular coagulation (DIC), pulmonary edema and anuria on admission were rejected.

The cases treated with vasopressors, inotropic agents and mechanical ventilation during the initial two hours or with death imminent within 24 hours were also rejected.

Date of first enrolment

01/06/2001

Date of final enrolment

31/10/2005

Locations

Countries of recruitment

China

Study participating centre
1-1 Zhong-fu Road
Nanjing
China
210003

Sponsor information

Organisation

The Second Hospital of Nanjing, affiliated with Medical College, Southeast University (China)

ROR

<https://ror.org/04pge2a40>

Funder(s)

Funder type

Government

Funder Name

The Health Office of Jiangsu Provincial Government, China

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	17/04/2008		Yes	No