ISRCTN36748319 https://doi.org/10.1186/ISRCTN36748319

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

Submission date
26/05/2006

Registration date
13/06/2006

Last Edited
05/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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.

Study design
Randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/06/2001

Completion date
31/10/2005

Eligibility

Key inclusion criteria
Patents 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

Age group
Adult

Sex
Both

Target number of participants
90

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)

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Sponsor type
University/education

ROR
https://ror.org/04pge2a40

Funder(s)

Funder type
Government

Funder Name
The Health Office of Jiangus Provincial Govermment, China

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/04/2008		Yes	No