ISRCTN87720456 https://doi.org/10.1186/ISRCTN87720456

A Simplified Goal-directed Protocol Improves Clinical Outcomes in Patients with Septic Shock: A Randomized Controlled Trial

Submission date
24/11/2005

Recruitment status
No longer recruiting

Registration date
28/11/2005

Overall study status
Completed

Last Edited
15/05/2007

Condition category
Infections and Infestations

[_] 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

N/A

Study information

Scientific Title

Study objectives
We sought to evaluate whether a goal-directed protocol, without measurement of central venous oxygen saturation (ScVO2), would improve survival in patients with septic shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The institutional review board approved this study

Study design
A 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
Septic shock

Interventions
The patients with septic shock were randomly assigned to receive therapy with or without a written protocol utilizing central venous pressure, mean arterial pressure and urine output as therapeutic goals.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
ICU and in-hospital mortality

Secondary outcome measures
Length of ICU stay, length of hospital stay, and duration of mechanical ventilation.

Overall study start date
01/07/2003

Completion date
28/02/2004

Eligibility

Key inclusion criteria
Patients admitted to intensive care unit (ICU) with diagnosis of septic shock were included in this study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
224

Key exclusion criteria
Exclusion criteria included age less than 18 years, pregnancy, or the presence of an acute cerebral vascular event, acute coronary syndrome, acute pulmonary edema, status asthmaticus, cardiac dysrhythmias (as a primary diagnosis), active gastrointestinal hemorrhage, seizure, drug overdose, burn injury, trauma, a requirement for immediate surgery, uncured cancer, immunosuppression, do-not-resuscitate status, or patient or family refusal to participate.

Date of first enrolment
01/07/2003

Date of final enrolment
28/02/2004

Locations

Countries of recruitment
Taiwan

Study participating centre
199 Tun Hwa N. Road
Taipei

Taiwan
105

Sponsor information

Organisation
Chang Gung Memorial Hospital (Taiwan)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Government

Funder Name
NSC-92-2314-B-182A-069, National Science Council, Taiwan, R.O.C

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	01/12/2006		Yes	No