ISRCTN99675218 https://doi.org/10.1186/ISRCTN99675218

Effect of treatment with low-dose hydrocortisone on cirrhotic patients presenting with septic shock to the intensive care unit

Submission date
18/07/2005

Recruitment status
Stopped

Registration date
08/09/2005

Overall study status
Stopped

Last Edited
25/01/2011

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Yaseen Arabi

Contact details
P.O. Box 22490
King Fahad National Guard Hospital
ICU 1425
Riyadh
Saudi Arabia
11426
+966 1 252 0088 Ext 2498
yaseenarabi@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LG-9-12

Study information

Scientific Title

Study objectives
The use of hydrocortisone improves the survival of cirrhotics presenting with septic shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 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 in cirrhotics

Interventions
This a placebo-controlled double blind randomized controlled trial. The intervention is to give hydrocortisone versus palcebo. Ethic Committee approval date: 26/10/2003.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hydrocortisone

Primary outcome measure

28-all cause mortality

Secondary outcome measures
1. Intensive care unit (ICU) mortality
2. Hospital mortality
3. Reversal of shock
4. Vasopressor-free days
5. Mechanical ventilation-free days
6. Renal replacement free days
7. ICU length of stay
8. ICU acquired infection
9. Requirment and duration of vasopressor therapy

Overall study start date
01/04/2004

Completion date
01/04/2006

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Cirrhotic patients admitted to the Intensive Care Unit with septic shock

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Pure hypovolemia
2. Hemorrhagic shock
3. Known adrenal insufficiency
4. Prior steroid use
5. Do not resuscitate (DNR) order
6. Patients in terminal condition
7. Contraindication to steroids
8. Refused consent
9. Post-cardiac arrest
10. Patient unexpected to survive 24 hours

Date of first enrolment
01/04/2004

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
P.O. Box 22490
Riyadh
Saudi Arabia
11426

Sponsor information

Organisation
King Abdul Aziz City For Science and Technology (Saudi Arabia)

Sponsor details
P.O Box 6086
Riyadh
Saudi Arabia
11442
+966 1 4883444
gdrgp@kacst.edu.sa

Sponsor type
Research organisation

ROR
https://ror.org/05tdz6m39

Funder(s)

Funder type
Research organisation

Funder Name

King Abdul Aziz City for Science and Technology (Saudi Arabia)

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	14/12/2010		Yes	No