

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/01/2011	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 is a placebo-controlled double blind randomized controlled trial. The intervention is to give hydrocortisone versus placebo. 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. Requirement 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

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Sponsor type

Research organisation

ROR

<https://ror.org/05tdz6m39>

Funder(s)

Funder type

Research organisation

Funder Name

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