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Physiological dose steroid therapy in sepsis

Submission date	Recruitment status	[_] Prospectively registered
15/04/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/04/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/02/2008	Infections and Infestations	

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
Protocol number: 97.02.20; Trial number: 97.013.46

Study information

Scientific Title

Study objectives
The aim of the study was to assess the prognostic importance of basal cortisol concentrations and cortisol response to corticotropin, and to determine the effects of physiological dose steroid therapy on mortality in patients with sepsis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the Institutional Review Board of Erciyes University and informed consent was obtained from the patients' relatives.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sepsis and adrenal insufficiencies

Interventions
Patients enrolled in the study were treated with standard therapy used in the treatment of sepsis and septic shock. This therapy could include administration of antibiotics, fluid replacement, vasoactive drugs, mechanical ventilatory support, and any other form of supportive therapy deemed necessary by the primary physicians.

Soon after the presumptive diagnosis of severe sepsis, an adrenalcorticotropic hormone (ACTH) stimulation test was performed with 250 µg of tetracosactrin (synacthene, Ciba Geigy, Germany) given intravenously and the patients were randomised to treatment with prednisolone or placebo groups. The treatment groups were determined by a computer-generated randomisation procedure.

Steroid therapy group received prednisolone in physiologic doses. Prednisolone was intravenously given 5 mg at 06.00 am, and 2.5 mg at 18.00 pm for ten days.

Standard therapy group received a placebo infusion containing physiologic saline solution in an identical manner.

Patients and their primary physicians were blinded as to which therapy was administered.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
The primary endpoint of the study was 28-day mortality from all causes.

Secondary outcome measures
The secondary endpoint consisted of adverse occurrences including possible complications of drug therapy and morbid events such as the progression of initial infection and the development of secondary infection. Secondary infection was defined as the identification of a new site of infection or the emergence of a different organism at the same site, generally requiring a change in antibiotic management.

Overall study start date
01/05/1997

Completion date
01/04/1999

Eligibility

Key inclusion criteria
Patients over 17 years old and diagnosed with sepsis were included in the study consecutively. The diagnosis of sepsis was based on the definition of the American College of Chest Physicians /Society of Critical Care Medicine Consensus Conference Report. The severity of illness was classified according to this definition.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
Criteria for exclusion from the study were as follows:
1. Already known pre-existing adrenal disease or adrenalectomy
2. Known malignancies, tuberculosis that might have involved the adrenal gland
3. Administration of steroids within the three months before the admission
4. In addition, patients with burns, hemorrhagic shock or those who had suffered myocardial infarction were not included

Date of first enrolment
01/05/1997

Date of final enrolment
01/04/1999

Locations

Countries of recruitment
Türkiye

Study participating centre
Erciyes Universitesi Tip Fakültesi
Kayseri
Türkiye
38039

Sponsor information

Organisation
Erciyes University (Turkey)

Sponsor details
Tip Fakültesi
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Sponsor type
University/education

ROR
https://ror.org/047g8vk19

Funder(s)

Funder type
University/education

Funder Name
Erciyes University (Turkey) - research fund (ref: 97.013.46)

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	01/06/2002		Yes	No