

Physiological dose steroid therapy in sepsis

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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 adrenalcorticotrophic 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Üniversitesi Tıp Fakültesi

Kayseri

Türkiye

38039

Sponsor information

Organisation

Erciyes University (Turkey)

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

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