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The effects of Immunoglobulin M (IgM) enriched immunoglobulin preparations in patients with severe sepsis

Submission date 29/04/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2002	**Overall study status** Completed	
Last Edited 07/03/2008	**Condition category** 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

N/A

Study information

Scientific Title

Study objectives
To evaluate the effect of IgM-enriched immunoglobulin treatment on progression of organ failure and septic shock in patients with severe sepsis.

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
Severe sepsis

Interventions
Patients in the study group (n = 21) received intravenous immunoglobulin preparation (Pentaglobin®) in addition to standard therapy. Pentaglobin® was started on the day of diagnosis of severe sepsis. 5 mL/kg/day Pentaglobin® (38 g/L IgG, 6 g/L IgM and 6 g/L IgA) was infused over 6 hours and repeated for three consecutive days.

Patients in the control group (n = 18) received standard sepsis therapy, but no immunoglobulin administration. Blood samples for procalcitonin measurements were taken daily for eight days. Severity of critical illness and development of organ failures were assessed by obtaining daily Acute Physiological and Chronic Health Evaluation II and Sequential Organ Failure Assessment scores.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pentaglobin®

Primary outcome measure
Procalcitonin (PCT) measurements; blood samples were taken daily for eight days following study admission.

Secondary outcome measures
1. Severity of critical illness, assessed by obtaining daily acute physiological and chronic health evaluation score (APACHE II)
2. Sequential organ failure assessment (SOFA) score used to assess the development of organ failure
3. Duration of mechanical ventilation
4. Length of stay in the intensive care unit
5. Septic shock incidence
6. 28-day mortality rate

Overall study start date
01/01/2000

Completion date
01/01/2001

Eligibility

Key inclusion criteria
Thirty-nine patients with severe sepsis, defined as:
1. Temperature of greater than 38°C or less than 36°C
2. Heart rate of greater than 90 beats/min
3. Respiratory rate greater than 20/min or arterial carbon dioxide pressure (PaCO2) less than 32 mmHg
4. White blood cell count greater than 12000/mm^3 or less than 4000/mm^3
5. Documented infection and dysfunction of an organ or hypotension

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
39

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2001

Locations

Countries of recruitment
Türkiye

Study participating centre
IU Istanbul Tip Fakültesi Anesteziyoloji AD
Istanbul
Türkiye
34390 Fatih

Sponsor information

Organisation
Istanbul University (Turkey)

Sponsor details
Anesthesiology Department
Istanbul Medical Faculty
Istanbul
Türkiye
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Sponsor type
Hospital/treatment centre

Website
http://www.istanbul.edu.tr/english/

ROR
https://ror.org/03a5qrr21

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/08/2002		Yes	No