

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

Registration date
29/04/2002

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
07/03/2008

Condition category
Infections and Infestations

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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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/mm³ or less than 4000/mm³
5. Documented infection and dysfunction of an organ or hypotension

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 Tıp Fakültesi Anesteziyoloji AD
Istanbul
Türkiye
34390 Fatih

Sponsor information

Organisation
Istanbul University (Turkey)

ROR
<https://ror.org/03a5qrr21>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/08/2002		Yes	No