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Alterations of immunologic mediators during severe sepsis

Submission date	Recruitment status	[_] Prospectively registered
20/04/2006	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/06/2006	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2019	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00484146

Protocol serial number
LAVISS_01

Study information

Scientific Title
Alterations of immunologic mediators during severe sepsis

Study objectives
Severe sepsis induces significant changes in expression of insulin and toll-like receptors, cytokines, markers of apoptosis, and activation of t- and b-lymphocytes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Saxonian Chamber of Physicians on the 21st July 2006 (ref: EK-BR-15/06-1).

Primary study design
Observational

Study design
Prospective, open, clinical observational study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Severe sepsis

Interventions
Daily blood samples for 7 days

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Alterations of immunologic parameters

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Agreement with study procedures, informed consent
3. Fulfilling 3 out of 4 criteria of a systemic inflammatory response syndrome (SIRS)

4. Suspected or proven infection
5. Two or more sepsis-induced organ dysfunctions
6. Start of first sepsis-induced organ dysfunction within the last 36 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Non-agreement with study procedures
2. Sign of severe sepsis for more than 36 hours
3. Chronic immuno-compromizing diseases
4. Chronic therapy with anti-inflammatory drugs
5. Non-curable cancer diseases
6. Chronic renal failure with hemodialysis
7. Pregnant or breast feeding

Date of first enrolment
01/06/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Delitzscher Str. 141
Leipzig
Germany
04129

Sponsor information

Organisation
Urban Clinical Center of St Georg in Leipzig (Städt. Klinikum St. Georg, Leipzig) (Germany)

ROR
https://ror.org/02y8hn179

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Urban Clinical Center of St Georg in Leipzig (Städt. Klinikum St. Georg Leipzig) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration