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Cristalloid versus colloid in patients with severe sepsis and septic shock

Submission date	Recruitment status	[_] Prospectively registered
09/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/04/2006	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
KRISCOLL (in Dutch: KRIStalloid versus COLLoid)

Study objectives
To demonstrate whether there is difference in tissue oxygen tension and extravascular lung water while patients are being resuscitated with cristalloids or colloids combined with cristalloids.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Sepsis, Septic shock

Interventions
Subjects are assigned to be resuscitated either with cristalloids (sodium chloride 0.9%) or cristalloid combined with colloids (polyhydroxyethylstarch 10%) until resuscitation endpoints have been established.
Endpoints are an intrathoracal blood volume of >850 ml/m^2, a mean arterial pressure of >70 mmHg and a cardiac index of >3.0 l/min/m^2.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
The relation between the resuscitation regime and the tissue oxygen tension.
Furthermore the relation between the resuscitation regime and the amount of extravascular lung water, as well as the relation between the amount of extravascular lung water and the tissue oxygen tension.

Secondary outcome measures
1. Subcutaneous temperature
2. Laboratory findings: hemoglobin, hematrocrite, albumin, arterial and venous blood gasses
3. Hemodynamic parameters: cardiac output, VO2, DO2
4. Respiratory parameters: PEEP, PaO2/FiO2 ratio; inotropes

Overall study start date
14/11/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Sever sepsis or septic shock (according to the criteria of the American College of Chest Physicians/Society of Critical Care Medicine) in a mechanically ventilated ICU patient.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Patients under the age of 18 years and patients with a sensitivity to starch-products.

Date of first enrolment
14/11/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Centre Utrecht
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Sponsor information

Organisation
University Medical Center Utrecht (The Netherlands)

Sponsor details
P.O. Box 85500
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3508 GA

Sponsor type
Not defined

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
University/education

Funder Name
University Medical Centre Utrecht, Department of Surgery

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