

Cristalloid versus colloid in patients with severe sepsis and septic shock

Submission date 09/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/04/2006	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 $>850 \text{ ml/m}^2$, a mean arterial pressure of $>70 \text{ mmHg}$ and a cardiac index of $>3.0 \text{ l/min/m}^2$.

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, hematocrite, 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
Utrecht
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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