

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
Registration date 09/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2006	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

1. Subcutaneous temperature
2. Laboratory findings: hemoglobin, hematocrite, albumin, arterial and venous blood gasses
3. Hemodynamic parameters: cardiac output, VO_2 , DO_2
4. Respiratory parameters: PEEP, $\text{PaO}_2/\text{FiO}_2$ ratio; inotropes

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

Utrecht

Netherlands

3584 CX

Sponsor information

Organisation

University Medical Center Utrecht (The Netherlands)

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

University/education

Funder Name

University Medical Centre Utrecht, Department of Surgery

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration