Cristalloid vs. colloid in patients with severe sepsis and septic shock.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21828

Source
NTR

Brief title
KRISCOLL (in Dutch: KRIStalloid vs. COLLoid)

Health condition

Severe sepsis or septic shock.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: The Department of Surgery of the University Medical Centre in Utrecht.

Intervention

Outcome measures

Primary outcome

The relation between the resuscitation regime and the tissue oxygen tension.
Furthermore the relation between the resuscitation regime and the amount of extravascular lungwater, as well as the relation between the amount of extravascular lungwater and the tissue oxygen tension.

Secondary outcome

1. Subcutaneous temperature;
2. Labaratory findings: hemoglobine, hematrocrite, albumine, arterial and venous bloodgasses;
3. Hemodynamic parameters: cardiac output, VO2, DO2;
4. Respiratory parameters: PEEP, PaO2/FiO2 ratio; inotropes.

Study description

Background summary

N/A

Study objective

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

Study design

N/A

Intervention

Subjects are assigned to be resuscitated either with cristalloids (sodiumchloride 0,9%) or cristalloid combined with colloids (polyhydroxyethylstarch 10%) untill rescusitation endpoints have been established.
Endpoints are an intrathoracal blood volume of > 850 ml/m2, a mean arterial pressure of > 70 mmHg and a cardiac index of > 3.0 l/min/m2.

Contacts

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Eligibility criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2005
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	11-11-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL460
NTR-old	NTR501
Other	: N/A
ISRCTN	ISRCTN25391663

Study results

Summary results

N/A