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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

## 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

## 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 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(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, hematrocrite, albumin, arterial and venous blood gasses
3. Hemodynamic parameters: cardiac output, VO2, DO2
4. Respiratory parameters: PEEP, PaO2/FiO2 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
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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