

# Effect of Hydrocortisone Treatment modality on Glycemic Control in patients with Septic Shock

<b>Submission date</b> 14/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2007	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

**Acronym**

HTGCSS

### **Study objectives**

Continuous hydrocortisone infusion will reduce the fluctuations in blood glucose levels in septic shock patients when compared to bolus treatment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics committee of Päijät-Häme Central Hospital, approval gained on 25th February 2005 (Code Q 71).

### **Study design**

Randomised prospective trial. Patients are randomised to receive hydrocortisone either by bolus or by continuous infusion in blocks of four patients. Study is not blinded nor placebo controlled.

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Vasopressor-dependent septic shock

### **Interventions**

Septic shock patients who are considered to benefit from the corticosteroid treatment are randomly assigned to receive hydrocortisone either by bolus treatment or by continuous infusion with equivalent dose (200 mg/day). During the study period a strict normoglycemic goal is maintained with continuous insulin infusion. Duration of hydrocortisone treatment was five days.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Hydrocortisone

### **Primary outcome(s)**

Mean blood glucose levels in study groups and the number of hyperglycemic (more than 7 mmol/l) and hypoglycemic (less than 3 mmol/l) episodes.

### **Key secondary outcome(s)**

Shock reversal during the five day study period and the amount of nursing workload needed to maintain normoglycemia.

### **Completion date**

30/04/2006

## Eligibility

### Key inclusion criteria

Septic shock patients meeting the criteria for septic shock according to the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference.

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

1. Patients under 18 years of age
2. Patients with diabetes
3. Patients receiving glucocorticoids

### Date of first enrolment

05/07/2005

### Date of final enrolment

30/04/2006

## Locations

### Countries of recruitment

Finland

### Study participating centre

Kuopio University Hospital

Kuopio

Finland

70211

## Sponsor information

### Organisation

Päijät-Häme Central Hospital (Finland)

ROR

<https://ror.org/02v92t976>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Medical Research Fund of Tampere University Hospital (Finland)

**Funder Name**

Medical Research Fund of Päijät-Häme Central Hospital (Finland)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/01/2007		Yes	No