

# 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

HTGCCS

## 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

05/07/2005

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

48

**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)

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### 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

## 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

## Study outputs

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