ISRCTN98820688 https://doi.org/10.1186/ISRCTN98820688

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

Submission date 14/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/10/2006	**Overall study status** Completed	
Last Edited 28/11/2007	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Esko Ruokonen

Contact details
Kuopio University Hospital
PO Box 1777
Kuopio
Finland
70211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 commitee 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 treament 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
Keskussairaalankatu 7
Lahti
Finland
15850
+358 3 81911
pekka.loisa@phks.fi

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?
Results article	Results	01/01/2007		Yes	No