ISRCTN53054042 https://doi.org/10.1186/ISRCTN53054042

HydroCortisone in Severe Acute Pancreatitis

Submission date 15/10/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/12/2008	**Overall study status** Stopped	
Last Edited 17/01/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-002346-30

Protocol serial number
EudraCT:

Study information

Scientific Title
Supraphysiologic hydrocortisone in severe acute pancreatitis: a multicentre, randomised, double-blind, placebo-controlled trial

Acronym
HC-SAP

Study objectives
Supraphysiologic doses of hydrocortisone may result in earlier reversal of shock and thus lead to faster recovery from multiple organ dysfunction syndrome and better survival in patients with severe acute pancreatitis and shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Department of Surgery in the Hospital District of Helsinki and Uusimaa has approved study protocol on the 8th September 2008 (ref: 193/13/03/02/08)
2. National Agency for Medicines has approved study protocol on the 4th October 2008 (KLnro: 108/2008)

Primary study design
Interventional

Study design
Multicentre randomised double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute pancreatitis

Interventions
Continuous intravenous infusion of hydrocortisone 300 mg/24 hours for 5 days, then 150 mg/24 hours for 3 days and then 50 mg/24 hours for 4 days. Placebo group receives infusion of comparable volume of physiologic saline for 12 days. Venous blood samples are collected before start of intervention and on days 1, 2, 3, 4, 5, 7, 14, 21 and 28 after randomisation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hydrocortisone

Primary outcome(s)
Intensive Care Unit (ICU) free days within first 60 days after randomisation.

Key secondary outcome(s)
1. Survival without vasopressor support within 60 days after randomisation
2. Requirement of vasopressor treatment (area under curve [AUC] of norepinephrine dose) for 5

days after randomisation
3. Organ failure free time (days with Sepsis-related Organ Failure Assessment [SOFA]-score less than 5) within 60 days after randomisation
4. Ventilator free days within 60 days after randomisation
5. Days free from renal replacement therapy within 60 days after randomisation
6. Mortality at day 28 and day 90 after admission to hospital
7. Changes of inflammatory mediators, markers of coagulation and serum free cortisol during ICU stay
8. Incidence of infected pancreatic necrosis

Completion date
31/10/2012

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with severe acute pancreatitis
2. Despite adequate fluid resuscitation (pulmonary capillary wedge pressure [PCWP] greater than 12 or central venous pressure [CVP] greater than 8 mmHg) presence of shock requiring vasopressor (norepinephrine greater than 0.2 µg/kg/min) support for at least one hour
3. Aged 18 to 65 years, both genders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Lack of written informed consent from patient or next of kin
2. Time from admission to hospital over seven days
3. Vasopressor support continued without interruption over 48 hours
4. Aged less than 18 years or greater than 65 years
5. Pregnancy or breastfeeding
6. More than two previous attacks of acute pancreatitis
7. Chronic pancreatitis or presence of complication after previous acute pancreatitis like pseudocyst
8. Hepatitis B, hepatitis C or human immunodeficiency (HIV) infection

9. Presence of acute infection (urinary, pulmonary, skin or soft-tissue infection)
10. Major abdominal, thoracic or vascular surgery within last 30 days
11. Severe chronic liver disease
12. Severe heart failure

Date of first enrolment
01/12/2008

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
Finland

Study participating centre
Department of Gastroenterological Surgery
Helsinki
Finland
00029

Sponsor information

Organisation
Helsinki University Central Hospital (EVO) (Finland)

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Central Hospital (EVO) (Finland) - Research Funds

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration