

# HydroCortisone in Severe Acute Pancreatitis

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| <b>Submission date</b><br>15/10/2008   | <b>Recruitment status</b><br>Stopped          | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>04/12/2008 | <b>Overall study status</b><br>Stopped        | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>17/01/2019       | <b>Condition category</b><br>Digestive System | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2008-002346-30

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

EudraCT: 2008-002346-30

## 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)

**Study design**

Multicentre randomised double-blind placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/12/2008

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Target: 150. Final: 4.

**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)

**Sponsor details**

Department of Surgery  
Meilahti Hospital  
Haartmaninkatu 4  
PL 340  
Helsinki  
Finland  
00029

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hus.fi/>

**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**

**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