

HydroCortisone in Severe Acute Pancreatitis

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

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)

Study design

Multicentre randomised double-blind placebo-controlled trial

Primary study design

Interventional

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/02e8hzhf44>

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