

# Randomised double-blind placebo-controlled trial of intravenous antioxidant therapy in predicted severe pancreatitis

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/04/2009	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N0226121484

# Study information

## Scientific Title

### Study objectives

Either anti-oxidants are of benefit in acute pancreatitis in which case all patients with severe disease should have the benefit of this therapy or they are of no benefit and should no longer be used.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### 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

Pancreatitis

### Interventions

Multi-centre, randomised double-blind placebo-controlled trial:

Group A - Maximal conventional therapy plus intravenous anti-oxidants for 7 days

Group B - Maximal conventional therapy plus placebo

### Intervention Type

Supplement

### Phase

Not Applicable

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

N-acetylcysteine, selenium, vitamin C

**Primary outcome measure**

Change in multiple organ dysfunction score.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

03/02/2003

**Completion date**

03/02/2005

## Eligibility

**Key inclusion criteria**

In total 150 patients with predicted severe acute pancreatitis and approx 75 controls will be recruited over the four centres. Approximately 30 patients at SMUHT.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

225

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

03/02/2003

**Date of final enrolment**

03/02/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Department of Surgery**  
Manchester  
United Kingdom  
M23 9LT

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

South Manchester University Hospitals NHS Trust (SMUHT) (UK)

## **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	01/10/2007		Yes	No