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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 27/04/2009	**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

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?
Results article	Results	01/10/2007		Yes	No