ISRCTN56033334 https://doi.org/10.1186/ISRCTN56033334

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Change in multiple organ dysfunction score.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

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

Results and Publications

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