

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/04/2009	Condition category Digestive System	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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