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A randomised controlled study of N-Acetylcysteine in liver transplantation

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 07/04/2011	**Condition category** Surgery	

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
N0544103857

Study information

Scientific Title

Study objectives
N-Acetylcysteine in liver transplantation

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)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Surgery: Liver transplant

Interventions
Patients undergoing liver transplantation will be randomly allocated to the N-Acetylcysteine group or a control group (no treatment).
Treatment will commence during the liver transplant and continue for 5 days post-operatively.
Blood tests and liver biopsies will be taken during the study for analysis.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

N-Acetylcysteine

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/09/2001

Completion date
01/09/2007

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Added May 2008:
Adult patients (≥18years) undergoing liver transplant

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Added May 2008: 170 patients would give 90% power but trial stopped.

Key exclusion criteria
Added May 2008:
Allergy to n-acetyl cysteine

Date of first enrolment
06/09/2001

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Honorary Consultant Surgeon
Cambridge
United Kingdom
CB2 2QQ

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
Cambridge Consortium - Addenbrooke's (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