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Randomised trial of N-acetylcysteine in laparoscopic bariatric surgery

Submission date	Recruitment status	[X] Prospectively registered
20/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2016	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
King's College Hospital
Denmark Hill
London
United Kingdom
SE59RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The Effect of Intraoperative N-Acetylcysteine on Hepatocellular Injury During Laparoscopic Bariatric Surgery: A Randomised Controlled Trial

Study objectives
Administration of N-acetylcysteine before and during the period of liver retraction will prevent or decrease the degree of liver damage due to ischaemia-reperfusion injury during laparoscopic bariatric surgery.

As of 25/03/2009 this record was updated to include new trial dates; the initial trial dates were as follows:
Initial anticipated start date: 01/03/2008
Initial anticipated end date: 01/03/2010

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approval granted from the King's College Hospital Research Ethics Committee on the 21/07/2008, ref: 08/H0808/2
2. Medicines and Healthcare products Regulatory Agency (MHRA) approval

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Morbid obesity /non-alcoholic fatty liver disease

Interventions
Treatment group: N-acetylcysteine 150 mg/kg lean body weight, intravenously as an infusion during surgery
Control group: No intervention

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
N-acetylcysteine

Primary outcome measure
The extent of hepatocellular damage and its clinical effect, measured at post-operative days 1, 2, 3 and at 6 weeks post surgery.

Secondary outcome measures
To elucidate the mechanisms of intraoperative hepatocellular damage and the effects (if any) of N-acetylcysteine.

Overall study start date
01/04/2009

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Male or Female
2. Aged 18 to 65
3. National Institute of Clinical Excellence criteria for morbid obesity surgery: BMI >40 or BMI >35 with obesity related complications

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Pregnancy
2. History of chronic liver disease, including viral hepatitis, haemachromatosis, alcoholic liver disease or known alcohol intake >20g/day
3. Previous liver surgery, e.g., resection, orthotopic transplantation

4. Psychiatric illness, including anxiety, mood and eating disorders
5. Bleeding tendency or anticoagulant medications
6. Known allergies to N-acetylcysteine or related compounds

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
London
United Kingdom
SE59RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Denmark Hill
London
England
United Kingdom
SE5 9RS

Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
King's College Hospital NHS Foundation Trust (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	01/06/2016		Yes	No