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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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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
The extent of hepatocellular damage and its clinical effect, measured at post-operative days 1, 2, 3 and at 6 weeks post surgery.

Key secondary outcome(s))
To elucidate the mechanisms of intraoperative hepatocellular damage and the effects (if any) of N-acetylcysteine.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

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

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

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