

Randomised trial of N-acetylcysteine in laparoscopic bariatric surgery

Submission date 20/12/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 28/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/06/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr A G Patel

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

Additional identifiers

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