# Randomised trial of N-acetylcysteine in laparoscopic bariatric surgery

Submission date	Recruitment status  No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
20/12/2007				
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

Mr A G Patel

#### Contact details

King's College Hospital Denmark Hill London United Kingdom SE59RS

# 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	<b>Details</b> results	Date created Date added Peer reviewed? Patient-facing?			
Results article		01/06/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11	1/11/2025	No	Yes