# Randomised trial of N-acetylcysteine in laparoscopic bariatric surgery

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

**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