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Effect of N-acetylcysteine on liver recovery after resection

Submission date 17/07/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/08/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/08/2014	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Liver resection is surgical removal of a portion of the liver. It is the treatment for multiple cancerous and non-cancerous masses in the liver. After removing a part of the liver it has the ability to regenerate. In some laboratory and animal studies N-acetylcysteine, a medication commonly used in treatment of acetaminophen (a pain medicine) overdose, has shown the ability to improve liver regeneration after resection. This study will test this theory in humans.

Who can participate?
All adult patients who are undergoing a major resection of the liver.

What does the study involve?
Patients are randomly allocated to either receiving N-acetylcysteine after the liver resection or not receiving it. There are no other differences in the treatment.

What are the possible benefits and risks of participating?
The potential benefit is improved liver regeneration. Potential risks are side effects from receiving the medication.

Where is the study run from?
The Foothills Medical Center, Calgary, AB, Canada.

When is study starting and how long is it expected to run for?
The study ran from February 2007 until June 2012.

Who is funding the study?
Alberta Health Services (Canada).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of N-acetylcysteine on liver recovery after resection: a randomized clinical trial

Study objectives
The objective of this study is to determine whether N-acetylcysteine can reduce the incidence of postoperative liver dysfunction and the overall complication rate when administered following major hepatic resection (two or more Coinaud segments).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Conjoint Health Research Ethics Board, University of Calgary, 18/05/2010, ref. E18866

Study design
Randomized clinical trial, single institution, non-blinded

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
Decrease in liver failure after liver resection for any diagnosis

Interventions
Both randomized groups will undergo the same preoperative and intraoperative management. The only difference in postoperative management will be use of N-acetylcysteine infusion - 150 mg/kg of NAC in 200 ml of 5% glucose over 45 minutes upon arrival in the post-anaesthesia recovery room. Then 50 mg/kg of NAC in 500 ml of 5% glucose over 4 hours, followed by 100 mg /kg in 1000 ml of 5% glucose over the next 16 hours, followed by 100 mg/kg in 1000 ml of 5% glucose per day over the next 3 days, which will be administered in six infusions of 50 mg/kg in 500 ml of 5% glucose, given over 12 hours each (intervention group only)

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Overall complication rate. These will be recorded in a prospective fashion throughout the trial. Coding will then be done according to the Clavien-Dindo classification, which is the most common description of types of complications (grade I, II, IIIa, IIIb, IVa, IVb and V).

Secondary outcome measures
Postoperative liver failure as defined by:
1. The 50-50 criterion (PT>50% (INR>1.7), bilirubin > 50 umol/l (3 mg/dL) on postoperative day 5)
2. Length of stay
3. Postoperative mortality

Overall study start date
01/02/2007

Completion date

01/06/2012

Eligibility

Key inclusion criteria
All adult patients scheduled to undergo major hepatic resection (defined as the removal of at least two Couinaud segments) for any cause at the Foothills Medical Centre who give written informed consent are eligible for the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
460

Key exclusion criteria
Participation in other trials before or during treatment

Date of first enrolment
01/02/2007

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Canada

Study participating centre
Division of General Surgery
Calgary, AB
Canada
T2N2T9

Sponsor information

Organisation
Alberta Health Services (Canada)

Sponsor details
10101 Southport Rd SW
Calgary, AB
Canada
T2W3N2

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02nt5es71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Alberta Health Services (Canada)

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