

Effect of N-acetylcysteine on liver recovery after resection

Submission date 17/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/08/2014	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Elijah Dixon
Elijah.Dixon@albertahealthservices.ca

Contact information

Type(s)

Scientific

Contact name

Dr Elijah Dixon

Contact details

Division of General Surgery
Faculty of Medicine
University of Calgary
EG - 26, Foothills Medical Centre
1403 - 29 Street NW
Calgary, AB
Canada
T2N2T9
+1 (0) 403 944 3045
elijah.dixon@albertaheathservices.ca

Additional identifiers**Protocol serial number**

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 Couinaud 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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/02nt5es71>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Alberta Health Services (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration