

Comparison of two anesthetic gases on liver and kidney in hepatitis C patients

Submission date 29/10/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/11/2015	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Hepatitis is a disease where the liver becomes inflamed (swollen), and is generally caused by a viral infection or long-term alcohol abuse. Hepatitis C is the most common type of viral hepatitis. In an infected person, the hepatitis C virus is particularly concentrated in the blood, and so it can be easily spread through blood-to-blood contact, such as sharing needles amongst drug abusers or receiving contaminated blood products in hospital. In the early stages (acute hepatitis) a person often has no symptoms, and so does not know that they are infected. This means that about 80% of infections are able to move to the long-lasting stage. Chronic hepatitis C (CHC) is where a person has been infected for more than six months. Sufferers tend to feel extremely tired, achy and generally unwell. Left untreated, the infection causes the liver to become irreversibly scarred (cirrhosis) leading to liver failure. People suffering from hepatitis C are also prone to other medical problems. Gallstones (solid lumps that develop from substances in the gallbladder) are very common in cirrhotic patients. Gallstones can be very painful and sometimes it is necessary to surgically remove the gallbladder (laparoscopic cholecystectomy). Patients with CHC are considered to have a greater risk of developing complications from surgery than the general population. The level of risk is determined using a scale called the Childs-Pugh score, where class A patients are very likely to survive and class B and C are less so. General anaesthesia (sedation) also puts patients at risk, as some of the drugs commonly used can be toxic to the liver and kidneys. More research is therefore needed to find the safest anaesthetic to use in surgery for patients with CHC. The aim of this study is to compare the effects of sevoflurane and desflurane (two inhalable anaesthetics) on liver and kidney function in CHC patients having a laparoscopic cholecystectomy.

Who can participate?

Adults with hepatitis C graded as class A using the Childs-Pugh score, who are scheduled for a laparoscopic cholecystectomy.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are sedated using sevoflurane and oxygen during their surgery, and the second group are sedated using desflurane and oxygen. Both drugs are given in the form of an inhalation anaesthetic (to be breathed in through a face mask) in their surgery for up to 2 hours. Participants have blood

samples taken after their surgery, and then again after 1 and 3 days in order to test how well their liver and kidneys are working. The amount of the hepatitis C virus in the blood is also measured after the surgery and 3 days later.

What are the possible benefits and risks of participating?

Participants will not benefit directly from taking part; however their participating could help to improve the way future patients are treated. The risks of participating include the general risks associated with having a laparoscopic cholecystectomy and being sedated using a general anaesthetic.

Where is the study run from?

1. Kasr Al-Aini Teaching Hospital (Egypt)
2. Theodor Bilharz Research Institute (Egypt)

When is the study starting and how long is it expected to run for?

July 2015 May 2016

Who is funding the study?

Theodor Bilharz Research Institute (Egypt)

Who is the main contact?

Professor Hala Goma

Contact information

Type(s)

Scientific

Contact name

Prof Hala Goma

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effects of low flow sevoflurane versus low flow desflurane anesthesia on hepatic and renal functions in hepatitis C positive patients undergoing laparoscopic cholecystectomy surgery

Study objectives

The aim of this study is to follow up the effect of low flow Sevoflurane versus desflurane anesthesia on renal and liver function, and if the hepatic affection is associated with increase in viral replication in HCV positive class A (Childs-Hugh score) patients undergoing laparoscopic cholecystectomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Theodor Bilharz Research Institute, 17/06/2015, ref: FWA 0001609

Study design

Multi-centre single-blinded randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Hepatitis C

Interventions

Participants are randomly allocated to one of two groups:

Group 1: Participants are treated using sevoflurane at a concentration of $(1.0 \pm 0.2 \text{ MAC})$ as inhalation anesthetic with 100% oxygen for anesthesia for up to 2 hours during their laparoscopic cholecystectomy surgery. Total fresh gas flow of 5L/min, for up to 2 hours.

Group 2: Participants are treated using desflurane at a concentration of $(1.0 \pm 0.2 \text{ MAC})$ between 40 and 60 minutes during their laparoscopic cholecystectomy surgery. Total fresh gas flow of 5L/min, for up to 2 hours.

Following surgery, blood samples are taken to measure liver and kidney function, as well as Hepatitis C viral RNA. The blood tests are repeated after 1 and 3 days postoperative.

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

1. Seveoflurane 2. Desflurane

Primary outcome measure

1. Liver function is determined by measuring AST, ALT and alkaline phosphate in the blood postoperative, 1 day and 3 days postoperative
2. Kidney function is determined by measuring urea and creatinine in the blood postoperative, 1 day and 3 days postoperative

Secondary outcome measures

Hepatitis C viral RNA is measured using blood testing preoperative and 3 days postoperative.

Overall study start date

30/07/2015

Completion date

30/05/2016

Eligibility**Key inclusion criteria**

1. Aged 20-60 years
2. Hepatitis C virus positive
3. Grade A patients (Child-Pugh classification of liver disease) with liver enzymes below double fold of normal reference range
4. Scheduled for laparoscopic cholecystectomy surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Grade B or C (Child-Pugh classification of liver disease) or with liver enzymes [alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than double fold of normal reference range
2. BMI over 30
3. Chronic renal disease and renalinsufficiency (creatinine>1,5 mg dl-1)
4. Use of alcohol or drugs
5. Diabetes Mellitus

6. Hypertenion
7. Unstable angina pectoris
8. History of myocardial infarction within the last 6 months

Date of first enrolment

01/08/2015

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

Egypt

Study participating centre**Kasr Al-Aini Teaching Hospital**

27 Nafezet Sheem El Shafaey Street

Kasr El Ainy

Cairo

Egypt

11562

Study participating centre**Theodor Bilharz Research Institute**

El Nile Street

Warrak El Hadar

Giza

Egypt

12411

Sponsor information

Organisation

Theodor bilharz insitute

Sponsor details

Kornish El-Nile

WarakEl-Hadar

Imbaba 30

Giza

Egypt

12411

Sponsor type

Hospital/treatment centre

Website

https://healthresearchweb.org/en/egypt/ethics_1027

ROR

<https://ror.org/04d4dr544>

Funder(s)**Funder type**

Research organisation

Funder Name

Theodor Bilharz Research Institute

Results and Publications**Publication and dissemination plan**

Planned publication of results in a peer reviewed journal.

Intention to publish date

30/05/2018

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date