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

Submission date
29/10/2015

Recruitment status
No longer recruiting

Registration date
17/11/2015

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 is 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 sevonflurane 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 desfluraneanesthesia on renal and liver function, and if the hepatic affectionis 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 seveoflurane at a concentration of (1.0 ±0.2 MAC) as inhalation anesthestic 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 ±0.2 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. Choronic 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