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Occlusion of the portal liver vein to permit liver surgeries for liver cancer

Submission date
08/03/2017

Recruitment status
No longer recruiting

Registration date
13/03/2017

Overall study status
Completed

Last Edited
22/09/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hepatocellular carcinoma (HCC) is the most common type of liver cancer. This type of cancer starts in the liver (primary liver cancer). When other cancers spread to the liver it is known as secondary liver cancer. When possible, surgery is the main treatment because it still is the best options for treating primary and secondary liver cancer. As the liver is able to re-grow itself, surgeons are able to remove affected sections of the liver completely (liver resection). However, a certain amount of the liver must remain in order for the liver to re-grow. Patients who require a large section of their liver to be removed can undergo a portal vein embolization (PVE) which tries to get the liver to grow prior to a liver resection. A needle is placed through the skin into the liver and the blood vessel that has the largest amount of the tumour is embolized (cut off) by injecting an embolizing material (that is similar to glue). This tricks the liver into regrowing on the side without the tumour. After a few weeks, enough of the liver should have grown in order to have the surgery to remove the cancerous area. There are different types of materials that can be injected into the blood vessel to embolize it such as n-butyl-cyanoacrylate (NBCA) which is a liquid embolic material that usually is used as a tissue adhesive (glue). The aim of this study is to evaluate the efficacy of portal vein embolization (PVE) using n-butyl-cyanoacrylate (NBCA) through an ipsilateral approach as well as evaluate the accomplishment of liver surgery, patient out-come after hepatectomy and safety of the proposed PVE technique.

Who can participate?
Patients aged 5-75 who require a liver resection.

What does the study involve?
This study reviews the surgical outcomes of participants who have undergone a PVE and liver resection. After these procedures, participants are followed up with visits to the study centre every two weeks during the first month after the procedure and then every three months for the next five years. The follow up consists of scans of the liver and reviewing medical charts in order to assess how well the PVE worked in regrowing the liver and the overall health outcomes of the liver resection surgery.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
INCA - Brazilian National Cancer Institute (Brazil)

When is the study starting and how long is it expected to run for?
January 2011 to December 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jose Hugo Luz

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
Portal vein embolization with n-butyl-cyanoacrylate through an ipsilateral approach before major hepatectomy: single center retrospective analysis of 50 consecutive patients

Study objectives
The aim of this study is to evaluate the efficacy of portal vein embolization (PVE) with the n-butyl-cyanoacrylate (NBCA) through an ipsilateral approach as well as evaluate the accomplishment of liver surgery, patient out-come after hepatectomy and safety of the proposed PVE technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brazilian National Cancer Institute Ethics Board, 27/01/2017, ref: 64117317.2.0000.5274

Study design
Single-center retrospective review study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Primary and secondary liver cancer

Interventions
This retrospective review study consists of participants that have been referred to have a portal vein embolization. Participants have the procedure which includes involves an ultrasounded guided puncture of the liver to gain access to the right portal vein. The occlusion of the port vein is obtained using n-butyl-cyanoacrylate (NBCA). The participant is then observed at the hospital for 24 hours and is discharged after.

Some time after the procedure (around a few weeks) participants undergo surgery to remove part of their liver. This is done to the standard level of care.

After the PVE and the surgery participants attend the study centre every two weeks during the first month following the procedures and after again then every three months for five years (participants can attend more follow up sessions if it is required).

The study centre visits consist of follow up from the attending physicians (surgeons or interventional radiologists). The follow up visits includes undergoing Volume CT scans and reviewing medical charts to assess the success of the portal vein embolization and the hepatectomy. Participants are followed up at regular periods for five years or when it is needed.

Intervention Type
Procedure/Surgery

Primary outcome measure
Growth of the future liver remnant is measured using the Future Liver Remnant (FLR) volume changes, growth rate and kinetic growth rate obtained from the Volumetric Computer Tomography of the liver at one and four weeks after portal vein embolization.

Secondary outcome measures
1. Accomplishment of hepatectomy is measured using patients medical charts at weeks four to six after portal vein embolization
2. Patient out-come after hepatectomy is measured using patients medical charts at baseline, week two, week four and every three months for five years
3. Safety of the proposed PVE technique measured using patients medical charts during their hospitalization stay after portal vein embolization

Overall study start date
01/01/2011

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients with primary and secondary liver cancer treatable by hepatectomy
2. Proportion of FLR volume to the total functional liver volume (TFLV) less than 25% or less than 40% in patients with previous chemotherapy or hepatic cirrhosis.
3. Aged between five to 75 years old

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
50

Key exclusion criteria

1. Extensive ipsilateral tumor precluding safe access to the portal vein
2. Unmanageable coagulopathy
3. Extensive extra-hepatic disease
4. Liver abscess or infection

Date of first enrolment
01/02/2011

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Brazil

Study participating centre
INCA - Brazilian National Cancer Institute
Praça Cruz Vermelha
23 Centro
Rio de janeiro
Brazil
20230-130

Sponsor information

Organisation
National Cancer Institute of Brazil INCA

Sponsor details
Praça Cruz Vermelha
23 Centro
Rio de Janeiro
Brazil
20230-130

Sponsor type
Hospital/treatment centre

Website
http://www2.inca.gov.br/wps/wcm/connect/inca/portal/home

ROR
https://ror.org/055n68305

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/04/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr José Hugo Mendes Luz jluz@inca.gov.br

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2017		Yes	No