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Treatment for primary liver cancer – initial experience with a new device in a Brazilian Cancer Center

Submission date
08/10/2016

Recruitment status
No longer recruiting

Registration date
14/10/2016

Overall study status
Completed

Last Edited
01/03/2019

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. It grows a large number of blood vessels that get most of their blood supply from the hepatic artery (one of the main arteries to the liver) . As the rest of the liver tissue gets it blood supply from the portal vein, doctors can treat HCC by cutting off the blood supply to the tumour using a technique called transarterial chemoembolization (TACE). This involves injecting the arteries feeding the liver tumour with a material, often a gelatin sponge which may be soaked with a chemotherapy drug, to block the artery. The sponge traps the chemotherapy inside the liver so that they are concentrated where the tumours are. DEB-TACE is a new way type of TACE whereby special beads containing the chemotherapy drugs are injected into the hepatic arteries and are then slowly released to threat the tumours. It is possible that DEB-TACE is less toxic (harmful) than standard methods and have fewer side effects. This study is looking at whether DEB-TACE is as successful at treating HCC as these other TACE methods.

Who can participate?
Patients aged 18 or over with HCC.

What does the study involve?
All participants are treated with DEB-TACE. They undergo at least 2 sessions of treatment, 2 months apart. All other treatment sessions after this are performed according to results of regular magnetic resonance imaging (MRI) or computed tomography (CT) assessments. All patients are followed up to see how they progress over the next two years. This includes checking for evidence of toxicity both during the DEB-TACE procedure and afterwards, looking at how the tumour responds to the treatment though MRI or CT and assessing for how long it is after treatment before the tumour begins to grow again.

What are the possible benefits and risks of participating?
The potential benefits are to achieve an effective treatment of the disease with much less toxic consequences than other treatment methods. The risks in being submitted to this new treatment are the occurrence of rare, but possible, unexpected side effects.

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

When is the study starting and how long is it expected to run for?
August 2009 to December 2010

Who is funding the study?
INCA - Brazilian National Cancer Institute

Who is the main contact?
Dr Jose Hugo Luz
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Approval #078/09

Study information

Scientific Title
DEB TACE for intermediate and advanced hepatocellular carcinoma (HCC) – initial experience in a Brazilian Cancer Center

Study objectives

Treatment of hepatocellular carcinoma with anew device known as drug-eluting beads may offer an at least equal result to standard TACE with significantly less toxicity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brazilian National Cancer Institute (INCA) Ethics Committee, 13/07/2009, ref: 078/09

Study design
Prospective non-randomized phase II study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
The interventions (Procedures called DEB TACE - Transarterial chemoembolization with drug-eluting beads), were done by a staff member of the interventional radiology team with experience with oncology interventions. Tow vials of the DEB TACE product DC Beads (2 mL, BioCompatibles Ltd., UK) with a diameter of 100 to 300 µm or 300 to 500 µm were loaded, per vial, with 75 mg of doxorubicin hydrochloride (37,5 mg/mL). Through the common femoral artery and using a diagnostic catheter (e.g. Cobra 5F) a microcatheter was placed as near as possible to the vessel irrigating the hepatic tumor. After a secure point was achieved by the tip of the microcatheter, researchers proceeded with the injection of the DC Beads loaded with doxorubicin mixed with contrast media and in a smooth fashion. The endpoint was to administer the whole two DC Beads vials or when flow of the tumor-nourishing artery reduced markedly. Total stasis of the tumor vascularity was avoided so it wouldn’t disturb the subsequent DEB TACE sessions.

The DEB TACE procedures were done at 2-month intervals during the first two sessions. From this point on new DEB TACE sessions were performed on demand accordingly to response in magnetic resonance (MR) and clinical outcome. Tumor response was evaluated with liver dedicated dynamic-enhanced MR of the abdomen and interpreted by body-imaging radiologists. Patients unable to perform MR were schedule to undergo computed tomography (CT). Clinical and laboratory tests were performed before and after each session and during hospitalizations, targeting the evaluation of the toxicity and quantification of adverse effects.

There was no control group.

Intervention Type
Device

Phase
Phase II

Primary outcome measure
1. Tumor response, assessed via magnetic resonance imaging (MRI) or computed tomography (CT) if patient not able to withstand MRI
2. Progression-free survival, via clinical assessments performed at least every three months over a two year period

Secondary outcome measures
Toxicity, evaluated during the DEB TACE procedure, immediately after it and during hospital permanence. Assessed via telephone calls and regularly scheduled hospital patient visits over a two year period

Overall study start date
01/08/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Patients 18 years old or above
2. Present with a Child A or B (Child-Pugh Classification) score
3. A PS equal or less than 2
4. A liver tumor compatible with a Barcelona clinic liver cancer (BCLC) stage B or C HCC which had not been previously submitted to transcatheter arterial chemoembolization (TACE) or any intra-arterial treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
21

Key exclusion criteria
1. Performance status scale (PS - Karnofsky performance status scale) of 2 or less
2. No extrahepatic spread of the liver tumor
3. Child-Pugh classification A or B
4. 17 years of age or younger
5. Refusal to sign the Informed consent

Date of first enrolment
01/08/2009

Date of final enrolment
01/01/2010

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
INCA - Brazilian National Cancer Institute

Sponsor details
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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
Government

Funder Name
INCA - Brazilian National Cancer Institute

Results and Publications

Publication and dissemination plan
Submission for a peer-reviewed oncology medical journal.

Intention to publish date

Individual participant data (IPD) sharing plan
Access to datasets are available upon request to Joana Emanuele (inca.interv@gmail.com) or Jose Hugo Luz (jhugoluz@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/02/2017		Yes	No