

Treatment of hepatocellular carcinoma with neoplastic thrombosis of the main portal vein using sorafenib and percutaneous radiofrequency ablation comparing to Sorafenib alone

| | | |
|--|---|---|
| Submission date 09/07/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/07/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/02/2019 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Hepatocellular cancer (HCC) is the most common type of liver cancer. It often develops in patients that have a liver disease (such as a viral hepatitis infection) or cirrhosis. There are a number of treatment options for liver cancer, particularly if it is diagnosed early. Radiofrequency ablation (RFA) is a treatment whereby radio waves can be used to destroy the cancerous cells and causing the tumour to shrink. Chemotherapy is another option, particularly at for more advanced stages of the disease as it has been shown to slow down progression. This study is looking at the three year survival rate for HCC patients with advanced disease involving main portal vein tumor thrombus (where the main blood vessel from the liver is partially blocked by a tumor) treated with RFA and sorafenib (a drug used to treated advanced liver cancer) compared with HCC patients that are treated only with sorafenib

Who can participate?

Adult patients with HCC with main portal vein tumor thrombus (MPVTT)

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 undergo RFA treatment for both their HCC and portal vein tumor thrombus tumors; the number of RFA sessions depend upon the size of the tumors. They are also treated with sorafenib. Those in group 2 are treated with sorafenib alone. All patients are followed up at 12, 24 and 36 months after the treatment

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
A total of 5 hospitals in Italy.

When is the study starting and how long is it expected to run for?
September 2010 to June 2014

Who is funding the study?
D. Cotugno Hospital (Italy)

Who is the main contact?
Dr Antonio Giorgio
agiorgio28@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Antonio Giorgio

Contact details
Viale Colli Aminei 491
Naples
Italy
80131

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SORAFENIB2011

Study information

Scientific Title
Sorafenib combined with percutaneous radio-frequency ablation of both hepatocellular carcinoma nodule and portal vein tumor thrombus compared with sorafenib alone: a western randomized controlled trial

Study objectives
To verify if the combination of percutaneous radiofrequency ablation (RFA) of both intraparenchymal hepatocellular carcinoma (HCC) and oral sorafenib is superior to oral sorafenib alone on increasing 3 years survival rate in patients with cirrhosis and HCC and invasion of main portal vein (MPV).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of D. Cotugno Hospital for infectious diseases, Naples, Italy, 11/04/2011

Study design

Interventional randomized controlled multicenter trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Hepatocellular carcinoma in cirrhosis

Interventions

Participants are randomly allocated to one of two groups:

1. RFA (radiofrequency ablation) of MPVTT (main portal vein tumor thrombus) and HCC (hepatocellular carcinoma) nodules plus sorafenib (combination group)
2. Sorafenib alone (sorafenib alone group)

Allocation was carried out prospectively with the use of a coded list compiled from a random number generator; the code was fully blinded to the field staff and trial participants were blinded to the code. The sample size was calculated considering 44% 3-year survival rate in the control group (Sorafenib alone) and assuming that the experimental group (RFA-MPVTT plus Sorafenib) would obtain more than a 20% increase in survival. An alpha error of 0.05 and a study power of about 80% (beta=0.20) were considered. The number of patients per arm was calculated to be more than 37 patients per arm.

RFA (percutaneous radiofrequency ablation) of MPVTT (main portal vein tumor thrombus) was performed under unconscious sedation by the same physician (A.G.) with more than 30 years' experience in interventional US and all percutaneous procedures were performed within 7 days of diagnosis. RFA of portal vein tumor thrombus (PVTT) was performed as reported elsewhere. Briefly, RFA of MPVTT was performed under US guidance using a perfused electrode-needle, (caliber 15 G, exposed tip 1.5-2.0 cm, according to the thrombus width) connected to an RF generator at a power of 80-100 Watt for 5-8 minutes: when the portal trunk appeared completely hyperechoic, the RFA application was considered sufficient and the electrode needle was withdrawn with the RF generator still on, so as to avoid seeding. RFA of the portal thrombus

was carried out firstly on the thrombus in the portal vein, taking care to avoid hepatic artery and common bile duct, and then on the hepatocellular carcinoma (HCC) intrahepatic nodule/s.

The number of sessions for ablation of both HCC nodules and MPVTT was scheduled as follows: one session in case of HCC nodules up to 3 cm and MPVTT length no more than 1.5 cm; two sessions in case of HCC nodules up to 5 cm and MPVTT length no more than 2.5 cm; 3 sessions in case of HCC nodules up to 6.5 cm and MPVTT length no more than 3.5 cm. The day after percutaneous RFA procedures all patients underwent clinical and laboratory tests and abdominal US.

After RF ablation HCC nodule's necrosis was evaluated using enhanced triphasic computed tomography (CT), while the recanalization of portal vessels was analyzed using color Doppler and CEUS.

Follow-up:

All patients underwent post-treatment follow-up, starting from the first day after the procedure through clinical evaluation and laboratory exams, abdominal US/Color Doppler/CEUS; than every week for the first 4 weeks all patients underwent abdominal US/Color-Doppler evaluation. during the following 36 months were made abdominal US/Color Doppler/CEUS and CT scan evaluation monthly, abdominal US and serum assay of AFP every 2 months and CEUS and CT scan every 6 months.

Intervention Type

Procedure/Surgery

Primary outcome measure

The survival rate, expressed in months, after 12, 24 and 36 months from treatment.

Secondary outcome measures

N/A

Overall study start date

01/09/2010

Completion date

04/06/2014

Eligibility

Key inclusion criteria

1. Child-Pugh A 5-6 liver cirrhosis
2. A single HCC nodule < 6.5 cm in diameter and concomitant main portal vein tumor thrombus (MPVTT)
3. Maximum 3 HCC nodules with the largest one no more than 5 cm with MPVTT

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50 patients for each arm

Key exclusion criteria

1. Patients with ascites
2. Patients with bilirubin >2 mg/dl
3. Patients and with extrahepatic spread of disease

Date of first enrolment

07/06/2011

Date of final enrolment

30/06/2014

Locations**Countries of recruitment**

Italy

Study participating centre

D. Cotugno Hospital for Infectious Diseases

Interventional Ultrasound Unit

Napoli

Italy

80131

Study participating centre

Tortorella Clinical Institute

Italy

84121

Study participating centre

Athena Clinical Institute

Italy

81016

Study participating centre

Gragnano Hospital

Italy

80054

Study participating centre
Ostuni Hospital
Italy
72012

Sponsor information

Organisation
D. Cotugno Hospital

Sponsor details
Via Quagliariello
Naples
Italy
80100

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
D. Cotugno Hospital (Italy)

Results and Publications

Publication and dissemination plan
Publish results on scientific journals with impact factor and to talk about results at scientific congresses (national and international) within the next year.

Intention to publish date
01/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/11/2016 | | Yes | No |