

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

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<b>Registration date</b> 26/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/02/2019	<b>Condition category</b> 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

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## 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?
<a href="#">Results article</a>	results	01/11/2016		Yes	No