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Sustained release particle of 5-fluorouracil combining transcatheter arterial chemoinfusion to treat hepatocellular carcinoma with portal vein tumour thrombus

Submission date 30/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/09/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/09/2008	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Sustained release particle of 5-fluorouracil (Sinofuan®) combining transcatheter arterial chemoinfusion to treat hepatocellular carcinoma with portal vein tumour thrombus: a randomised controlled trial

Study objectives
The prognosis of patients with hepatocellular carcinoma (HCC) accompanied by portal vein tumour thrombus (PVTT) is generally poor. A literature review regarding transcatheter arterial chemoinfusion (TAC) was difficult due to differences in techniques, patient selection, and underlying liver function. In fact, this was an exclusion criterion for some treatments.

Sinofuan® is a newly approved fluorouracil sustained release particle for HCC in China. It can steadily release fluorouracil for hundreds of hours and maintains effective concentration around its implanting site. Because the portal vein tumour thrombus is mainly composed of tumour tissue, it is supposed that the direct implantation of Sinofuan® into the thrombus should result in a better outcome than single TAC therapy. This trial is designed to examine this hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Affiliated 10th People's Hospital, Tongji University (China) on the 5th March 2008.

Study design
Single-centre, non-blinded, randomised, controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Hepatocellular carcinoma/portal vein tumour thrombus

Interventions

1. Intervention: percutaneously implant the sustained release particle of 5-fluorouracil in the tumour thrombus and treat HCC with TAC
2. Control: single treatment of HCC with TAC

For the intervention group, the sustained release particle of 5-fluorouracil will be percutaneously implanted once and only once. Within one week, TAC will be performed to treat HCC. The total duration of treatment will be no more than one week. The duration of follow-up is six months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
5-fluorouracil (Sinofuan®)

Primary outcome measure
1. Patient dies, measured at one month and six months
2. Disappearance of portal vein thrombus, measured at one month

Secondary outcome measures
1. Closure of portal vein lateral flow, measured at one and two months
2. Decreased size of thrombus less than or equal to 20% of original, measured at one month, two months, four months and six months

Overall study start date
17/03/2008

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Image-proven HCC
2. Irresectable tumour
3. Failure to previous treatment
4. Child-Pugh scale less than or equal to 10
5. Aged 30 - 80 years, either sex
6. Tumour thrombus is proven within portal vein and its section area exceeds 50% of vessel by computed tomography (CT)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Uncontrolled hypertension
2. Unstable angina
3. Arrhythmias requiring treatment
4. Myocardial infarction (MI)
5. Congestive heart failure or cardiomyopathy requiring treatment

Date of first enrolment
17/03/2008

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
China

Study participating centre
YanChang Road, 301
Shanghai
China
200072

Sponsor information

Organisation
Affiliated 10th People's Hospital of Tongji University (China)

Sponsor details
YanChang Road, 301
Shanghai
China
200072

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/03vjkf643

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Affiliated 10th People's Hospital of Tongji University (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration