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The effect of ischaemia/reperfusion injuries by pringle manoeuvre on the prognosis of hepatocellular carcinoma patients after radical excision

Submission date 25/07/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/08/2008	**Overall study status** Completed	
Last Edited 14/02/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00725335

Protocol serial number
swhb001

Study information

Scientific Title
The effect of ischaemia/reperfusion injuries elicited by pringle manoeuvre on the prognosis of hepatocellular carcinoma patients after radical excision: a multicentre prospective randomised study

Study objectives
Until now there are two popular procedures during the radical excision of primary liver cancer in China. One is to give a pringle manoeuvre to control the operative blood loss and the other is to use a combination of CUSA and TissueLink to control the bleeding in patients without liver ischaemia. According to recent experimental studies in rats, we know that ischaemia and reperfusion injury may contribute to the metastasis of the tumour, so we hypothesised that ischaemia and reperfusion injuries during the surgery may accelerate the outgrowth of liver cancer cells and affect the survival of the patients. In order to test the actual contribution of ischaemia on humans, we are conducting this prospective clinical trial to compare the two popular procedures' effect on the prognosis of liver cancer patients undergoing radical excision.

Please note that as of 08/09/2008 the actual start date of the trial is 09/09/2008. The previous anticipated start date of the trial was 15/08/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the Ethics Committee of Southwest Hospital as of 28/07/2008.

Study design
Treatment, parallel assignment, two-armed randomised, actively controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hepatitis B virus related primary hepatocellular carcinoma

Interventions
Experimental group: radical excision of liver cancer without liver ischaemia
Control group: radical excision of liver cancer under pringle manoeuvre

The total duration of follow-up for all treatment arms will be five years after the first radical excision operation.

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
1. Disease free survival, measured 1, 3 and 5 years after the first radical excision operation
2. Total survival, measured 1, 3 and 5 years after the first radical excision operation

Key secondary outcome(s))
1. Liver function test, measured at each follow-up timepoint, that is 1, 2, 4, 6, 8, 12, 16, 20, 24, 30, 36, 42, 48, 54 and 60 months after the first radical excision operation
2. Hospital stay, measured during peri-operation period
3. Intensive care unit stay, measured during peri-operation period

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Current as of 11/09/2008:
The following changes have been made to the below two points of the inclusion criteria:
4. Hepatitis B surface antigens (HBsAg) positive
5. Tumour nodes in the liver can be radically excised

Initial inclusion criteria:
1. Aged from 18 to 65 years, without gender restriction
2. Clinical diagnosis of resectable primary liver cancer
3. The liver function tests showed: Child-Pugh grade A; clearance of indocyanine green at 15 minutes (CICG-R15) of 20%
4. Hepatitis B surface antigens (HBsAg) positive, hepatitis B deoxyribonucleic acid (HBV-DNA) less than 100,000 copies/ml
5. No more than two tumour nodes in the liver
6. No preoperative anti-cancer therapy
7. Written informed consent from the patient or legal guardian prior to entering the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Pregnancy
2. With extrahepatic tumour or lymph node metastasis
3. Tumour invasion or thrombosis in portal vein, hepatic vein or inferior vena cava
4. Surgical marginal positive

Date of first enrolment
09/09/2008

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
China

Study participating centre
Institute of Hepatobiliary Surgery
Beijing
China
100000

Sponsor information

Organisation
Institute of Hepatobiliary Surgery of PLA, Southwest Hospital (China)

ROR
https://ror.org/043sbvg03

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institute of Hepatobiliary Surgery of PLA, Southwest Hospital (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/08/2012	14/02/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes