

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00725335

Secondary identifying numbers

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

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 to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

09/09/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

c/o Feng Xiaobin

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30 Gaotanyan Street
Shapinba District
Chongqing
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400038

Sponsor type

University/education

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

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

Study outputs

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