

# A randomised clinical trial evaluating the benefits of doxorubicin chemoembolisation (CEM) versus systemic doxorubicin in patients with unresectable, advanced hepatocellular carcinoma (HCC)

<b>Submission date</b> 24/08/2005	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-different-ways-of-giving-chemotherapy-for-primary-liver-cancer>

## Study website

<http://www.hep1.bham.ac.uk>

## Contact information

### Type(s)

Scientific

### Contact name

Prof James Garden

### Contact details

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

NCT00079027

**Secondary identifying numbers**

HE3001

## **Study information**

**Scientific Title**

**Acronym**

HEP-1

**Study objectives**

To test the hypothesis that patients with advanced, unresectable HCC treated with CEM will have an improved survival compared to those treated with single agent Doxorubicin.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

Patient information can be found at: <http://www.hep1.bham.ac.uk/HEP1-PatientGeneralInfo-v1.5.pdf>

**Health condition(s) or problem(s) studied**

Unresectable, advanced hepatocellular carcinoma

## Interventions

Control Arm: Single agent doxorubicin, max dose 60 mg/m<sup>2</sup> IV day 1, repeated once every 3 weeks for a max of 6 cycles

Treatment Arm: Chemoembolisation (CEM) using doxorubicin, repeated every 8 weeks for a max of 3 procedures

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Doxorubicin

## Primary outcome measure

Survival

## Secondary outcome measures

1. Overall Response (determined by RECIST criteria)
2. Time to progression (determined by RECIST criteria)
3. Toxicity
4. QoL
5. Health economics
6. Proteomics
7. Immunological

## Overall study start date

01/10/2005

## Completion date

01/10/2010

## Reason abandoned (if study stopped)

Objectives no longer viable

# Eligibility

## Key inclusion criteria

1. Histological or cytological diagnosis or The European Association for the Study of the Liver (EASL) criteria met for unresectable HCC
2. No prior systemic or regional chemotherapy
3. Aged greater than or equal to 18 years (or greater than or equal to 16 years in Scotland)
4. Laboratory parameters:
  - 4.1. Haemoglobin (Hb) greater than or equal to 8.5 g/dl
  - 4.2. Platelets greater than or equal to 100,000/mm<sup>3</sup>
  - 4.3. Absolute neutrophil count (ANC) greater than or equal to 1500/mm<sup>3</sup>
  - 4.4. International normalised ratio (INR) less than 1.5
  - 4.5. Bilirubin less than or equal to 50 µm/L
  - 4.6. Transaminases less than 2.5 x upper limit of normal (ULN)

- 4.7. Serum creatinine less than 2 x ULN
5. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2
6. Modified Pugh's Child B grade or better
7. Not of childbearing potential or using an approved method of contraception
8. Written informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

280

**Key exclusion criteria**

1. New York Heart Association (NYHA) Class III/IV cardiac disease
2. Left ventricular ejection fraction (LVEF) of less than 50% or acute anginal symptoms
3. Thrombosis of main portal vein
4. Main portal vein occlusion/involvement
5. Patients whom in the opinion of the investigator have 'clinically significant ascites'
6. History of second malignancy within 5 years prior to trial entry, excepting cervical carcinoma-in-situ or non-melanotic skin cancer
7. Previous chemotherapy, radiotherapy, biological or hormone therapy given for hepatocellular carcinoma
8. Any ablative therapy for hepatocellular carcinoma within the last 6 weeks. Radiological evidence of progression is required if assessing a previously ablated site as the only site of disease.
9. Use of other investigational agent during the study or within 4 weeks of planned study entry
10. Major surgery within 7 days or laparoscopy within 3 days of trial entry
11. A serious co-existing medical condition including a potential serious infection or significant peripheral vascular disease
12. Psychological, familial, sociological or geographical factors considered likely to prevent compliance with the protocol
13. Presence of extrahepatic tumour of any kind

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

01/10/2010

**Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**The University of Edinburgh**

Edinburgh

United Kingdom

EH16 4SA

## **Sponsor information**

**Organisation**

The University of Birmingham and University of Edinburgh (UK)

**Sponsor details**

Research & Enterprise Services

Muirhead Tower

University of Birmingham

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

**Sponsor type**

University/education

**Website**

<http://www.cancerstudies.bham.ac.uk/trials/>

**ROR**

<https://ror.org/01nrxf90>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: C9041/A4578)

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **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