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

Submission date	Stopped	[X] Prospectively registered		
24/08/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/09/2005 Last Edited	Stopped Condition category	Results		
		☐ Individual participant data		
17/05/2012	Cancer	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

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00079027

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Unresectable, advanced hepatocellular carcinoma

Interventions

Control Arm: Single agent doxorubicin, max dose 60 mg/m^2 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(s)

Key secondary outcome(s))

- 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

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^3
- 4.3. Absolute neutrophil count (ANC) greater than or equal to 1500/mm^3
- 4.4. International normalised ratio (INR) less than 1.5
- 4.5. Bilirubin less than or equal to $50 \mu m/L$
- 4.6. Transaminases less than 2.5 x upper limit of normal (ULN)
- 4.7. Serum creatinine less than 2 x ULN
- 5. Eastern Coooperative 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

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 carcinomain-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

United Kingdom

Scotland

Study participating centre
The University of Edinburgh
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation

The University of Birmingham and University of Edinburgh (UK)

ROR

https://ror.org/01nrxwf90

Funder(s)

Funder type

Charity

Funder Name

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

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes