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

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

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

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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^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 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^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 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 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

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/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, 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