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A randomised, open label controlled trial of trans-arterial chemoembolisation vs embolisation alone in non-resectable hepatocellular carcinoma

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 26/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-treatment-for-primary-liver-cancer-that-cannot-be-removed-with-surgery

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0256130934

Study information

Scientific Title
A randomised, open label controlled trial of trans-arterial chemoembolisation vs embolisation alone in non-resectable hepatocellular carcinoma

Acronym
TACE

Study objectives
To investigate whether there is a difference in terms of overall survival, time to progression, response rate, quality of life and toxicity between the two treatment arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open-label active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Liver cancer

Interventions
Current information as of 11/08/2009:
Single centre phase III randomised controlled trial comparing trans-arterial chemoembolisation

vs embolisation alone
1. Treatment arm - trans-arterially administered cisplatin followed by embolisation
2. Control arm - Embolisation only

Initial information at time of registration:
Single centre phase III randomised controlled trial comparing trans-arterial chemoembolisation vs embolisation alone

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
1. Overall survival
2. Quality of life
3. Toxicity
4. Objective response rates

Secondary outcome measures
Not provided at time of registration

Overall study start date
14/10/2003

Completion date
30/04/2008

Eligibility

Key inclusion criteria
Added 11/08/2009:
1. Evidence of HCC as diagnosed by either histological means; or as evidenced by a focal lesion >2 cm with arterial hypervascularisation detected on two radiological studies (any two of ultrasound, CT, MRI or angiography) in a patient with a background of cirrhosis; or by a single radiological study with an a-fetoprotein greater than 400 ng/ml (1)
2. The patient must not be a candidate for surgical resection of the tumour but may be suitable for transplantation
3. The patient must have either a solitary hepatic tumour >3 cm in diameter or multifocal disease as evidenced by CT or MRI scanning.
4. Aged ≥16 years and estimated life expectancy >3 months
5. ECOG performance status ≤ 2
6. Adequate haematological function
7. Adequate clotting function: INR ≤ 1.5
8. GFR ≥ 50ml/min
9. Adequate liver function

10. Capable of giving written informed consent
11. Women of child-bearing potential should have a negative pregnancy test prior to study entry AND be using an adequate contraception method, which must be continued for 3 months after completion of treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
196

Key exclusion criteria
Added 11/08/2009:
1. Extra-hepatic metastases
2. Prior treatment for HCC
3. Active sepsis or bleeding
4. Hepatic encephalopathy
5. Ascites refractory to diuretic therapy
6. Documented occlusion of the hepatic artery or portal vein
7.Hypersensitivity to intravenous contrast agents
8. Pregnant or lactating women
9. History of prior malignancy
10. Any evidence of severe or uncontrolled systemic diseases or laboratory finding
11. Any psychiatric or other disorder (eg brain metastases) likely to impact on informed consent

Date of first enrolment
14/10/2003

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hampstead NHS Trust
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK)

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?

Plain English results			No	Yes
Results article	results	02/04/2013	Yes	No