ISRCTN11889464 https://doi.org/10.1186/ISRCTN11889464

ImmunoTACE

Submission date 28/10/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 11/12/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/09/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-using-chemotherapy-a-cancer-vaccine-and-chemoembolisation-for-liver-cancer

Contact information

Type(s)
Scientific

Contact name
Prof David Adams

Contact details
I-ACT Team,
CRCTU, 5th Floor East,
Institute of Translational Medicine,
Heritage Building,
Mindelsohn Way,
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

Clinical Trials Information System (CTIS)
2011-001690-62

Protocol serial number
VERSION 9 : RG_10-148

Study information

Scientific Title
A randomised phase II clinical trial of conditioning cyclophosphamide and chemoembolisation with or without vaccination with dendritic cells pulsed with hepg2 lysate in vivo in patients with hepatocellular carcinoma (HCC)

Study objectives
Current study hypothesis as of 12/02/2019:
To determine whether activity due to the addition of dendritic cells (DC) vaccine to chemoembolisation and preconditioning prolongs progression free survival (PFS) and warrants further investigation.

Previous study hypothesis:
To determine whether activity due to the addition of dendritic cells (DC) vaccine to chemoembolisation and preconditioning cyclophosphamide warrants further investigation in a large randomised phase III clinical trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK National Ethics committee - NRES Committee West Midlands - Coventry and Warwickshire; Ref: 11/WM/0367

Primary study design
Interventional

Study design
Phase II randomised trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hepacellular Carcinoma

Interventions
Dendritic cell vaccine, Cyclophosphamide, TACE (standard treatment)

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Progression Free survival time at every visit

Key secondary outcome(s)

Current secondary outcome measures as of 12/02/2019:
1. Radiological response assessment (RECIST 1.1 criteria) measured at baseline, Day 60 and then every 3 months thereafter
2. Change in the tumour marker serum alpha-fetoprotein (AFP) at every visit
3. Assessment of toxicity using Common Terminology Criteria for Adverse Events (CTCAE) (version 4) at every visit
4. Immune response at every visit
5. Overall survival time
6. Radiological response based on modified RECISIT (mRECIST)
7. Progression free survival at 12 months where progression is determined by mRECIST

Previous secondary outcome measures:
1. Radiological response rate (RECIST criterion) measured at baseline, Day 60 and then every 3 months thereafter
2. Rate of change in the tumour marker serum alpha-fetoprotein (AFP) at every visit
3. Assessment of toxicity using National Cancer Institute common terminology criteria for adverse events version 4.02 (NCI-CTCAE version 4) at every visit
4. Immune response rate at every visit
5. Overall survival

Completion date
30/11/2020

Eligibility

Key inclusion criteria
Current participant inclusion criteria:
1. Histological or cytological diagnosis or meet the American Association for the Study of Liver Diseases (AASLD) criteria for diagnosis of HCC and at least one unidimensional lesion measurable according to the Response Evaluation Criteria In Solid Tumors 1.1 (RECIST 1.1) by CT-scan or MRI
2. Suitable for transcatheter arterial chemoembolization (TACE)
3. Aged >18 years and estimated life expectancy >6 months
4. Not a candidate for surgical resection or transplantation
5. No previous chemotherapy, radiotherapy, immunotherapy or other experimental treatment for HCC prior to entry into the trial
6. ECOG performance status <= 2
7. Adequate haematological function: Hb >9g/L, Absolute neutrophil count >1.5x109/L, platelet count >50x109/L
8. Bilirubin < 50 umol/L , AST or ALT < 5 x ULN
9. Adequate renal function: Cockroft and Gault estimation > 40ml/min
10. INR less than or equal to 1.5
11. ChildPugh score ≤ 7
12. Women of childbearing potential should have a negative pregnancy test prior to trial entry
13. Women of childbearing potential and men who have partners of childbearing potential must be willing to practise effective contraception for the duration of the study and for six months after the completion of treatment.
14. Written informed consent
15. Suitable veins for access with 17G fistula needle

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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 12/02/2019:
1. Extrahepatic metastasis
2. Prior embolisation, systemic or radiation therapy for HCC
3. Investigational therapy or major surgery within 4 weeks of trial entry
4. Any ablative therapy [radiofrequency ablation (RFA) or percutaneous ethanol injection (PEI)] for HCC [this should not exclude patients if target lesion(s) have not been treated and occurred >6 weeks prior trial entry]
5. Child Pugh score >7
6. Hepatic encephalopathy
7. Ascites refractory to diuretic therapy
8. Documented invasion of the main portal vein

9. Hypersensitivity to intravenous contrast agents
10. Active clinically serious infection >grade 2 NCI-CTC version 4.0 within preceding two weeks
11. Pregnant or lactating women
12. History of second malignancy except those treated with curative intent more than three years previously without relapse and nonmelanotic skin cancer or cervical carcinoma in situ
13. Evidence of severe or uncontrolled systemic diseases, congestive cardiac failure >NYHA class 2, myocardial infarction (MI) within 6 months or laboratory finding that in the view of the investigator makes it undesirable for the patient to participate in the trial
14. Psychiatric or other disorder likely to impact on informed consent
15. Known history of HIV
16. Patient is unable and/or unwilling to comply with treatment and trial instructions
17. Patients with active autoimmune disorder
18. Hypersensitivity to cyclophosphamide or to any of its metabolites
19. Current cystitis infection
20. Urinary outflow obstruction

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Date of first enrolment
06/01/2014

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Aintree University Hospital
Liverpool
United Kingdom
L9 7A

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - EME grant

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No