

ImmunoTACE

Submission date 28/10/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/09/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

2011-001690-62

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Phase II randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

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

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 measure

Progression Free survival time at every visit

Secondary outcome measures

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 RECIST (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

Overall study start date

06/01/2014

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 $>9\text{g/L}$, Absolute neutrophil count $>1.5 \times 10^9/\text{L}$, platelet count $>50 \times 10^9/\text{L}$
8. Bilirubin $< 50 \text{ umol/L}$, AST or ALT $< 5 \times \text{ULN}$
9. Adequate renal function: Cockcroft and Gault estimation $> 40\text{ml/min}$
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

Previous participant inclusion criteria:

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14. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

48

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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9. Hypersensitivity to intravenous contrast agents
10. Active clinically serious infection >grade 2 NCI-CTC version 4.0 (appendix 7) within preceding two weeks
11. Pregnant or lactating women
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Date of first enrolment

06/01/2014

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

England

United Kingdom

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)

Sponsor details

Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

It is intended that the results of this trial will be submitted for publication in a peer reviewed journal 12 months after the trial end date.

Intention to publish date

30/11/2021

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